United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

MAY 31 2002

Dr. Romano Marabelli
General Director
Department of Food and Nutrition and
Public Veterinary Health
Ministry of Health
Piazza Marconi, 20-00144
Rome, Italy

Dear Dr. Marabelli:

This letter transmits the Food Safety and Inspection Service (FSIS) final report of a meat inspection system audit conducted in Italy from November 14 through December 19, 2001. No comments on the draft final audit report were received from the Government of Italy.

All deficiencies noted during this audit have been corrected as evidenced by the FSIS audit conducted in April 2002. FSIS appreciates the actions taken by the Government of Italy to resolve the audit deficiencies. Please be advised that all final audit reports are posted on FSIS' website **www.fsis.usda.gov/ofo/tsc.**

If you have questions or need additional information, you may reach me at 202-720-3781, facsimile at 202-690-4040, or email at sally.stratmoen@fsis.usda.gov.

Sincerely,

Richard A. Brown

/S/Sally Stratmoen, Chief
Equivalence
International Policy Staff

Enclosure

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Country File (Italy—Nov 01 final audit)

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AUDIT REPORT FOR ITALY
NOVEMBER 14 THROUGH DECEMBER 19, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Italy's meat inspection system from November 14 through December 19, 2001. Forty of the 64 establishments certified to export meat to the United States and that were exporting to the United States were audited. Six of these were slaughter establishments; the other 34 were conducting processing operations. The remaining establishments that are certified to export to the United States were not actively exporting at this time and they were not included in this audit.

The last audit of the Italian meat inspection system was conducted in May 2001. The auditors found significant problems in 10 establishments, which were then designated as marginal/re-review at the next audit. The auditors found sanitation and other conditions to be so serious in eight establishments that these establishments were delisted by the Government of Italy (GOI). In addition, the auditors found that implementation of Hazard Analysis and Critical Control Point (HACCP) systems was deficient in 22 of 27 establishments audited.

The major concerns from the May 2001 audit were the following:

1. The lack of daily inspection coverage in establishments producing products for export to the U.S.
2. Inadequate inspection system controls, including the denaturing of condemned or inedible products, enforcement of humane slaughter laws, use of inspection procedures to check for disease, and carcass and offal inspection requirements.
3. Instances of actual product contamination and instances of the potential for direct product contamination.
4. The lack of monthly supervisory reviews of most certified establishments.
5. The continuing problems with the implementation and maintenance of Sanitation Standard Operating Procedures (SSOP) in certified establishments.
6. The continuing problems with implementation and maintenance of HACCP systems in certified establishments.
7. Deficiencies in the *Salmonella* sampling and testing program.
8. Deficiencies in Italy's microbiological laboratory testing programs.

Italy exports only processed pork products to the United States. Fresh pork may not be exported due to the presence of hog cholera and swine fever in Italy. From January 1 to

September 30, 2001, Italian establishments exported 3,593,523 pounds of pork products to the United States. Port-of-entry rejections were for unsound condition (0.02%), miscellaneous defects (0.05%), and missing shipping marks (0.05%).

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Italian national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second part involved on-site visits to 40 establishments: 34 processing establishments (5L, 23L, 25L, 41L, 90L, 151L, 160L, 172L, 205L, 316L, 335L, 363L, 368L, 442L, 476L, 480L, 492L, 500L, 513L, 514L, 550L, 586L, 632L, 649L, 683L, 688L, 714L, 720L, 744L, 758L, 989L, 1170L, 1217L, and 1223L) and six slaughter establishments (92M/S, 272M/S, 304M/S, 312M/S, 643M/S, and 791M/S). All six of Italy's certified slaughterhouses and another seven processing establishments were selected for audit because of serious concerns arising from the previous on-site audits. Twenty-seven additional establishments were selected randomly from certified establishments actively exporting to the United States. The third part involved visits to nine government laboratories, all of which culture field samples for the presence of generic *Escherichia coli* (*E. coli*) and *Salmonella*. Two of the nine laboratories also perform analytical testing of field samples for the national residue-testing program. The fourth part involved visits to six regional inspection offices and four local inspection offices.

Program effectiveness determinations focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of HACCP systems and the generic *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella*. Italy's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditors evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditors also determined if establishment and inspection system controls were in place.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the monthly reviews for compliance with U.S. specifications. A Ministry of Health (MOH) official requested that FSIS lead this current audit and FSIS agreed. In the future, MOH officials will lead the audits of the individual establishments.

RESULTS AND DISCUSSION

Summary

Forty establishments were audited. The auditors found sanitation and other conditions to be so serious in four establishments that the establishments were delisted by the GOI (160L, 363L, 500L, and 989L). The auditors found serious problems in five establishments. These establishments were designated as marginal/re-review during the next audit (172L, 492L, 649L, 744L, and 758L).

Six Regional Inspection Offices and four local inspection offices were visited. The seventh Regional Office declined the visit citing other commitments. The following six Regional Offices were visited: Lombardia, Lazio, Emilia-Romagna, Friuli-Venezia Guilia, Toscana, and Marche. Four local inspection offices were visited, one each within the following regions: Lombardia, Lazio, Emilia-Romagna, and Toscana.

As stated above, numerous major concerns had been identified during the May 2001 audit of the Italian meat inspection system. During this current audit, the auditors determined that no significant improvements were made by the GOI since the May 2001 audit. Some improvements were noted in individual establishments' implementation and operation of HACCP and SSOP. These improvements may be attributed to a working group formed by the MOH after the May 2001 audit to address the May 2001 audit findings or to training provided through Italian trade associations directly to establishment personnel. Despite the improvements noted, the Italian meat inspection system still has major deficiencies, which demonstrate a lack of government oversight as evidenced by the findings presented in this report.

Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* species and generic *E. coli*, are discussed later in this report. Data collection instruments for SSOP, HACCP, and testing programs for generic *E. coli* and *Salmonella* can be found in Attachments A, B, C and D respectively. Individual establishment reports can be found in Attachment F.

Entrance Meetings

On November 14, 2001, an entrance meeting was held at the Ministry of Health in Rome. The Italian government participants were Dr. Silvio Borrello, Dipartimento Alimenti Nutrizione E Sanita' Pubblica Veterinaria (DANSPV), Dirigente II Livello- Direttore Ufficio VIII; Dr. Pietro Noe, Veterinario Dirigente I Livello-Ufficio VIII, DANSPV; Dr. Piergiuseppe Facelli, Veterinario Dirigente II Livello, Direttore Ufficio III, DANSPV; Dr. Angelo Di Donato, Veterinario Dirigente I Livello, Ufficio III, DANSPV; Dr. Alessandra Di Sandro, Veterinario Dirigente I Livello, Ufficio VIII, DANSPV; Dr. Pinto Ornella, Veterinario Dirigente I Livello, Ufficio VIII, DANSPV; Dr. Alessandro Cascone, Veterinario Dirigente I Livello, Ufficio VIII, DANSPV; Dr. Lidia Cecio, Veterinario Dirigente I Livello, Ufficio VIII, DANSPV; Dr. Raffaella Augelli, Veterinario Coadiutore Ufficio VIII, and Ms. Marina Paluzzi, Interpreter.

The United States government participants were Dr. Faizur R. Choudry, International Audit Staff Officer, Technical Service Center (TSC), Food Safety and Inspection Service (FSIS); Dr. Oto Urban, International Audit Staff Officer, TSC, FSIS; Ms. Ann Murphy, Agricultural Attaché, United States Embassy, Rome; and Mr. Sandro Perini, Agricultural Specialist, United States Embassy, Rome.

Topics of discussion at the first entrance meeting included the following:

- Welcome by Dr. Silvio Borrello, Dirigente II Livello, and explanation of the Italian meat inspection system.
- Discussion of the previous audit report.
- The audit itinerary and travel arrangements.
- Training programs for veterinary meat inspection officials for pathogen reduction and other food safety initiatives such as SSOP, HACCP programs, generic *E. coli* testing and *Salmonella* testing.
- The auditors provided (a) a copy of the current Quarterly Regulatory and Enforcement Report, (b) FSIS Directive 6420.1, Livestock Post-mortem Inspection Activities-Enforcing the Zero Tolerances for Fecal Material, Ingesta, and Milk, and (c) FSIS Notice 22-01, Procedures for FSIS Personnel during Pre-implementation Period for "Retained Water in Raw Meat and Poultry Products; Poultry Chilling Requirements."

On November 26, 2001, a second entrance meeting was held at the Ministry of Health in Rome. The Italian government participants were Dr. Silvio Borrello, Dipartimento Alimenti Nutrizione E Sanita' Pubblica Veterinaria (DANSPV), Dirigente II Livello- Direttore Ufficio VIII and Dr. Piergiuseppe Facelli, Veterinario Dirigente II Livello, Direttore Ufficio III, DANSPV. The United States government participants were Dr. Ghias Mughal, Branch Chief, International Review Staff, FSIS, and Mr. Franco Regini, Agricultural Specialist, Foreign Agricultural Service, United States Embassy, Rome.

Topics of discussion at the second entrance meeting included the following:

- Welcome by Dr. Silvio Borrello, Dirigente II Livello, and explanation of the Italian meat inspection system.
- Discussion of the previous audit report.
- The audit itinerary and travel arrangements.

<u>Government Oversight and Responsibility</u>

FSIS regulations require that foreign countries that request eligibility to export meat to the United States or to maintain their current eligibility be organized and administered by the national government. More specifically, the National government must have an inspection system consisting of an organizational structure with staffing to ensure uniform enforcement of the requisite laws and regulations in all establishments producing product for export to the United States. Second, the national government must have ultimate control and supervision over the official inspection activities of all employees and licensees. Third, the national

government must ensure the assignment of competent, qualified inspectors. Fourth, national inspection officials must have the authority and responsibility to enforce the laws and regulations governing meat inspection, and fifth, the country must have adequate administrative and technical support to operate its inspection program.

Our auditors noted the following.

1. Organizational Structure and Staffing

The Italian meat inspection system is organized in three levels. The first level consists of the Ministry of Health, which includes Veterinary Services. It is this level of government that FSIS holds responsible for ensuring that FSIS requirements are implemented and enforced. The second level consists of Regional Offices. There are 21 Regional Offices (19 regions and two provinces). Each Regional Office is autonomous and independent from the MOH. Among Regional Offices, there are differences in organization, staffing and available resources. Within each Regional Office, a third level exists known as the Aziende Sanitarrie Locali (ASL), which are also autonomous. The ASLs provide the inspectors for actual inspection activities.

There are generally two levels of employment of inspectors and veterinarians at the ASLs and the Regional Offices. These two levels consist of a Director of the ASL or Region and staff veterinarians. Each level appears to be independent of the other. If a veterinarian assigned to the establishment fails to properly discharge his/her responsibilities, the Director seems to have little or no authority to take proper disciplinary action. The auditor was told that if such a situation arises, the MOH will decertify the establishment and the establishment may then sue the veterinarian to recover the damages.

All inspection veterinarians and inspectors in establishments certified by Italy as eligible to export meat products to the United States were MOH regional and local government employees, receiving no direct remuneration from either industry or establishment personnel.

The MOH has responsibilities for participating and negotiating new or revised inspection legislation, interpreting and clarifying inspection-related European Commission Directives, United States requirements and Italian laws and regulations, and transmitting these documents to the Regional Offices. Although compliance is requested by the MOH, each Regional Office and ASL may create their own corresponding circulars, forms, and instructions, provided they meet the minimum requirements outlined by the MOH.

Although an organizational structure is in place for headquarters, the Regional Offices, and the ASLs, staffing at the MOH and the Regional Offices appears inadequate. As stated above, Regional Offices vary in staffing and available resources. It appears that this inhibits the ability of the inspection officials to enforce European Commission Directives and U.S. inspection requirements.

2. Ultimate Control and Supervision

On November 6, 2001, the MOH sent a circular to all Regional Offices requesting that they develop inspection procedures as described in the circular and to adopt procedures and forms for inspection that meet the provisions in the circular. However, since the circular was only issued one week before our auditors arrived in Italy, the Regional Offices had not had time to implement the circular. In one Regional Office, the circular could not be located.

The supervision and authority delegated by each Regional Office and ASL varies. Our auditor found that government inspectors and veterinarians that work at the establishments are generally not accountable to the ASL, the Regional Office, or the MOH. The inspectors that actually perform the routine inspection activities are hired and paid by the ASL. The ASL or the Regional Office generally cannot discipline or fire poor performing employees but can only recommend action to the Director General of the ASL against such an employee.

Although detailed instructions are issued by the MOH for the Regions and the ASLs on requirements to be carried out by Regions or ASLs, including on-site visits to establishments, the MOH and the ASLs seems to rely heavily upon the results of FSIS audits of individual establishments rather than meeting the MOH's requirements. Italy's inspection system appears to be reactive for maintaining compliance rather than preventive. For example, the MOH verified compliance with U.S. requirements only in the slaughter establishments found unacceptable during the May 2001 audit. The MOH did not conduct any other verification activities with regard to determining compliance of processing establishments that were found to be unacceptable or marginal/re-review.

There appears to be no regular or uniform verification procedure by the MOH of the circulars sent to the Regional Offices and ASLs to assure that the circulars have been implemented. For example, two microbiology directors indicated their willingness and ability to perform analyses according to U.S. methodology. However, both also said that they had not been instructed by the MOH to implement U.S. methodology and would not change their procedures until requested to do so by the MOH.

3. Assignment of Competent, Qualified Inspectors

In 29 processing establishments, the GOI was not providing daily inspection coverage. Inspectors were visiting establishments at variable frequencies such as two to three times a week, once a week, twice a month, or once a month. In four of the regions audited, the auditor was told that there were not enough inspection resources to provide daily inspection coverage.

Once inspectors are assigned, the GOI does not have a uniform method to prioritize and assign inspection tasks. The performance of inspection tasks at an establishment is solely dependent upon the judgment of the inspector.

In all 40 of the establishments audited, the GOI inspectors were not aware of deficiencies until pointed out to them by the auditors. In addition, in nine of the 40 establishments GOI inspectors did not take corrective actions when deficiencies were discovered.

The auditor noted that all government veterinarians must have completed at least three years of specialized training in food inspection prior to hiring. Additionally, some Regional Offices have provided opportunities for formal training in HACCP and other food science disciplines. However, considerable training in basic sanitation principles and FSIS' Pathogen Reduction requirements is still needed. This need for additional training is evidenced by the fact that the majority of establishments continue to have serious problems with basic sanitation, which has resulted in direct product contamination and the potential for direct product contamination. In addition, the auditor found that most inspectors and veterinarians assigned to certified establishments do not understand how to implement or have not been required to implement FSIS' Pathogen Reduction requirements, which include SSOP, HACCP, generic *E. coli* testing, and *Salmonella* testing.

The auditor was advised that there is no supervision of inspectors and veterinarians in the Regional Offices and the ASLs. The auditor was told that all government veterinarians are expected to operate at a high level of professionalism and trust. The performance of these veterinarians is rarely questioned. Actual visits to determine competence by the Regional Office are not routinely performed or documented and are not part of any written supervisory plan.

4. Authority and Responsibility to Enforce the Laws

Prior to our May 2001 audit, ASLs had the responsibility for approving establishments for export to the U.S. and to withdraw such approval for cause. Subsequent to our May 2001 audit, the MOH assumed this responsibility. Under the direction of the MOH, any new establishment that wishes to export to the U.S. has 90 days to comply with U.S. requirements. The ASL monitors the establishment and then notifies the MOH, either through the Regional Office or directly, of the decision to certify or not certify the establishment for U.S. export. The MOH generally does not visit these establishments on-site but will certify the establishment based on the ASL's recommendation.

For example, an establishment in the Lazio Region, which had been delisted by the GOI at FSIS' recommendation during the May 2001 audit, was recertified prior to our November 2001 audit without verification of its acceptability by the MOH. This establishment had not undertaken any corrective actions since the last audit and was again found unacceptable by FSIS during this new audit. An establishment in the Marhe Region was certified by the MOH but was delisted just prior to the start of the current audit. When asked about the situation, the auditor was told that the establishment was decertified because the Regional Office had found some problems in the establishment that were not known to MOH at the time of certification. The MOH has advised that in the future it will verify the acceptability of all new establishments by conducting on-site visits to the establishments before they are certified for export.

The only change in the organizational structure or upper levels of the MOH was the hiring of five new staff officers (3 full time and 2 part time) subsequent to the May 2001 audit. This brings the total headquarters staff to six employees. The auditor was told that once training had been completed for these new employees, the MOH would be able to conduct monthly supervisory reviews of the U.S. certified establishments to verify the implementation of FSIS requirements.

5. Adequate Administrative and Technical Support

The auditors were concerned over the inability of the MOH to provide basic resources for the FSIS audit, which resulted in industry personnel transporting the auditors to the establishments. The allocation of appropriate resources to support a third party audit still remains.

Establishment Audits

Establishment Operations by Establishment Number

The following operations were being conducted in the 40 establishments visited on-site:

Pork slaughter and boning - six establishments (92M/S, 272M/S, 304M/S, 312M/S, 643M/S, and 791M/S)

Pork de-boning and prosciutto/cooked hams – 34 establishments (5L, 23L, 25L, 41L, 90L, 151L, 160L, 172L, 205L, 316L, 335L, 363L, 368L, 442L, 476L, 480L, 492L, 500L, 513L, 514L, 550L, 586L, 632L, 649L, 683L, 688L, 714L, 720L, 744L, 758L, 989L, 1170L, 1217L, and 1223L)

Forty establishments were visited. Four establishments (160L, 363L, 500L, and 989L) were found to be unacceptable because of critical sanitation problems, findings of direct product contamination, and noncompliance with basic HACCP requirements and were delisted by the GOI. Five establishments (172L, 492L, 649L, 744L, and 758L) were rated marginal/re-review because of deficiencies regarding sanitation, condition of facilities, and noncompliance with HACCP requirements.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information about the following risk areas was also collected:

1. Government oversight of accredited, approved laboratories.
2. Intra-laboratory quality assurance procedures, including sample handling.
3. Methodology.

The Instituti Zooproficlattici Sperimentali Laboratories in Torino and Brescia were audited on December 12 and 13, 2001, respectively. Both of these laboratories perform analytical testing of field samples for the national residue control program. Effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, and proficiency testing. The methods used for the analyses were acceptable. No compositing of samples was done. More detailed information on audit findings can be found under "Residue Controls" further in this document.

Italy's microbiological testing for *Salmonella* was being performed in government Instituti Zooproficlattici Sperimentali (IZS) laboratories. Nine of these laboratories were visited. The nine included the residue laboratories in Torino and Brescia as they also perform microbiological testing. Eight of these nine laboratories perform analyses for the GOI on product intended for export to the United States.

Italy has advised FSIS that it adopted all FSIS requirements except the following equivalent measures: The government laboratories use ISO 6579 and AOAC 967.25 methods to analyze samples for *Salmonella.* During the May 2001 audit, FSIS found that laboratories were using modified analytical methods that had not been sent to FSIS for an equivalence determination.

More detailed information on audit findings can be found under "Slaughter/Processing Controls" and "Enforcement Controls" further in this document.

SANITATION CONTROLS

As stated earlier, the auditor focuses on five areas of risk when assessing a foreign country's inspection system. The first of these risk areas that the auditor reviews is Sanitation Controls. These controls include the implementation and operation of SSOP programs in certified establishments, all aspects of facility and equipment sanitation, actual or potential instances of product cross-contamination, personal hygiene and practices, and product handling and storage.

Based on the on-site audits of establishments, Italy's inspection system had controls in place for water potability records; chlorination procedures; back-siphonage prevention; separation of operations; temperature control; work space; ventilation; ante-mortem facilities; welfare facilities; and outside premises.

In the following areas, inspection system controls were not adequate:

Sanitation Standard Operating Procedure (SSOP)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOP in the 40 establishments were found to meet the basic FSIS regulatory requirements, with the following deficiencies.

- In 31 establishments, GOI meat inspection officials were not adequately monitoring or verifying the adequacy and effectiveness of the pre-operational and operational sanitation SSOP. The inspectors were performing pre-operational and operational sanitation SSOP with variable frequencies, such as once a week, twice a month, once a month and four times a year. *This is a repeat deficiency from the May 2001 audit.*
- In 12 establishments, the records for SSOP operational sanitation and any corrective action taken were not being maintained. *This is a repeat deficiency from the May 2001 audit.*
- In three establishments, the written SSOP procedure did not address pre-operational sanitation. *This is a repeat deficiency from the May 2001 audit.*
- In three establishments, the written SSOP did not address operational sanitation. *This is a repeat deficiency from the May 2001 audit.*
- In two establishments, the SSOP procedure did not identify the individual responsible for implementing and maintaining the activities. *This is a repeat deficiency from the May 2001 audit.*

Cross-Contamination: In the area of cross-contamination, actual product contamination and the potential for product contamination was found in 26 out of 40 establishments audited.

Examples of findings of actual product contamination include:

- In nine establishments, insanitary equipment was directly contacting edible product in the processing rooms, fresh product receiving rooms, and cold boning rooms. For example, working tables and frames of tables, containers for edible product, meat grinding equipment, band saw, conveyor belt for edible product, brine injection equipment, racks, and molds for hams were found with flaking paint, rust, fat, pieces of meat, grease, and dirt from the previous days' operation. In some establishments, the conveyor belt for edible product was cracked and deteriorated in the salting rooms and product receiving room. This is a noncompliance with Council Directive 64/433/EEC of 26 June 1964. *In five of nine establishments, this is a repeat deficiency.*

- In nine establishments, exposed edible-product was contacting an unclean fork lift, inedible product containers, posts, dirty legs of racks for edible product that stacked on top of each other, unclean protective covering for air circulation system, walls and doors during handling and transportation in the de-boning rooms, ham salting rooms, ham curing rooms, and fresh ham receiving rooms. This is a noncompliance with Council Directive 64/433/EEC of 26 June 1964. *In four of nine establishments, this is a repeat deficiency.*

- In three establishments, dripping condensate from overhead refrigeration units, ceilings, rails, pipes, and beams that were not cleaned/sanitized daily, was falling onto exposed edible product in the cooler, fresh product receiving room, corridors, defrosting room,

cooking room, and smoking rooms. This is a noncompliance with Council Directive 64/433/EEC of 26 June 1964. *In two of three establishments, this is a repeat deficiency.*

- In three establishments, sanitizers were not maintained at the required temperature (82ºC) in the boning rooms. In one other establishment, the sanitizer was not in operation during processing operations. This is a noncompliance with Council Directive 64/433/EEC of 26 June 1964. *In two of three establishments, this is a repeat deficiency.*

- In one establishment, water was falling onto hog carcasses from the carcass splitting saw at the carcass splitting station. This is a noncompliance with Council Directive 64/433/EEC of 26 June 1964. *This is a repeat deficiency for this establishment.*

Examples of findings of <u>potential</u> cross-contamination of product include:

- In six establishments, overhead ceilings in the processing rooms and ham salting rooms were observed with an accumulation of pieces of fat, meat, flaking paint, and dirt. This is a noncompliance with Council Directive 64/433/EEC of 26 June 1964. *In one of six establishments, this is a repeat deficiency.*

<u>Personal Hygiene and Practices</u>: In the area of personal hygiene and practices, the following deficiencies were noted.

- In eight establishments, several employees were observed picking up pieces of meat from the floor, handling unclean inedible product containers, a fork lift, and trash containers and, without washing their hands, handling edible product.
establishments, plastic packaging materials, cartons, and strings for hanging hams were contacting the floor and inedible product containers in the packaging rooms.
establishment, a few employees were not using hygienic work habits. For example, paper towels were kept
another establishment, edible product was not unpacked in a sanitary manner to prevent

June 1964.

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exposed product contamination. In another establishment, street clothes and working clothes were not kept separate in the locker. This is a n
Directive 64/433/EEC of 26 June 1964.

<u>Product Handling and Storage</u>
deficiencies were noted.

- In 11 establishments, edible product that contacted the floor (dropped meat) was not reconditioned in a sanitary manner before being added to the edible product. The f
for reconditioning dropped meat was inadequate. There was no designated area with light, no written proper procedure, and no hand washing or sanitizing facilities. This is a

noncompliance with Council Directive 64/433/EEC of 26 June 1964. *In one of 11 establishments, this is a repeat deficiency.*

- In 11 establishments, edible and inedible product containers were not identified to prevent possible cross-contamination or cross utilization in the boning room, ham slicing room, and ham salting rooms, and processing rooms. *In two of 11 establishments, this is a repeat deficiency.*

- In eight establishments, pest control prevention was inadequate. For example, in one establishment, the dry storage room for packaging materials had no front and side walls (plastic curtains) to prevent the entry of rodents and other vermin. Mice droppings, urine, cobwebs, dirt and debris were observed and packaging materials were not stored on racks high enough and away from walls to monitor pest control and sanitation programs. Evidence of rodent infestation was observed on several dates in the personnel office and welfare rooms by a private pest control company during their routine monitoring program. Rodenticides were replaced in the bait boxes but no other effort was made to take corrective or preventive measures either by the pest control company, establishment personnel, or by the GOI meat inspection officials. In another establishment, the door in the product receiving room was not effectively shut. The vent in the smoking room was broken and flies were observed in the processing and packaging rooms. In five establishments, gaps at the bottoms and sides of doors in the boning rooms, casing rooms, product receiving rooms, emergency doors leading to the processing rooms, and dry storage rooms were not sealed properly to prevent the entry of rodents and other vermin. In one other establishment, cobwebs were observed in the ham curing room. This is a noncompliance with Council Directive 64/433/EEC of 26 June 1964. *In one of eight establishments, this is a repeat deficiency.*

Establishment Facilities: In the area of maintenance of establishment facilities, the following deficiencies were noted.

- In four establishments, light was inadequate and not shadow proof at the hog head, viscera and carcass inspection stations in the slaughter room. *In two out of four establishments, this is a repeat deficiency.*

- In one establishment, walls and covings were broken in numerous places in the coolers and processing rooms. This is a noncompliance with Council Directive 64/433/EEC of 26 June 1964.

ANIMAL DISEASE CONTROLS

The second of the five risk areas that the auditor reviews is Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. Except as noted below, Italy's inspection system had adequate controls in place.

There were reported to have been no outbreaks of animal diseases with public health

approximately 100,000 bovine were tested for Bovine Sponigiform Encephalopathy and 30 were found positive. Italy is prohibited from exporting beef to the U.S. In addition, Italy is not free from Hog Cholera or Swine Vesicular Disease. Although Italy is currently free of

border with a country that is not free of Foot and Mouth Disease.

The following deficiencies were noted.

In two out of six slaughter establishments, the mandibular lymph nodes of hog heads

lymph nodes and spleen were not palpated during post mortem inspection. This is a noncompliance with Council Directive 64/433/EEC of 26 June 1964. *This is a repeat deficiency from the May 2001 audit.*

- In all 40 establishments, inedible product was not denatured or de-characterized or placed under security before shipping for rendering. In one establishment, inedible product was kept in open containers outside the premises. *This is a repeat deficiency from the May 2001 audit.*

RESIDUE CONTROLS

The third of the five risk areas that the auditor reviews is Residue Controls. These controls include sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

The Instituti Zooproficlattici Sperimentali (IZS) Laboratories in Torino and Brescia were audited on December 12 and 13, 2001, respectively.

The following deficiencies were noted.

- The standards book for chlorinated hydrocarbons, polychlorinated biphenyls, trace elements, hormones, sulfonamides, chloramphenicol, and ivermectin was not properly maintained for the quality assurance program. For example, when the analyst prepares the solutions, the standards book was not signed and verified by the supervisor before the solutions were used. Corrections to the standards book were not made by means of a single line through the incorrect entry with the correct information written above or after the error.

- When percent recovery results fell below the established acceptable range limit for chlorinated hydrocarbons, polychlorinated biphenyls (PCBs), hormones, arsenic, and chloramphenicol, no corrective actions were taken or documented for the quality

assurance program. *This is a repeat deficiency from the May 2001 audit with regard to percent recovery for PCBs.*

- The check sample program did not meet FSIS or EU requirements. In most sections of the laboratories, regular spiked samples that are routinely run as part of a sample set were erroneously considered to be check samples. No intra-laboratory and/or inter-laboratory check samples for the quality assurance program were performed for chlorinated hydrocarbons, polychlorinated biphenyls, trace elements, hormones, sulfonamides, chloramphenicol, antibiotics, and ivermectin except for one inter-laboratory check sample (ring test) was performed for polychlorinated biphenyls and trace elements in 2001. This is a noncompliance with Council Directive 96/23/EC of 29 April 1996.

The auditors found that Italy's National Residue Testing Plan for 2001 was being followed and was on schedule. The GOI had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals. The methods used for the analyses were acceptable.

SLAUGHTER/PROCESSING CONTROLS

The fourth of the five risk areas that the auditor reviews is Slaughter/Processing Controls. The controls include the following areas: adequate animal identification; ante-mortem inspection procedures; ante-mortem disposition; humane slaughter; post-mortem inspection procedures; post-mortem disposition; ingredients identification; control of restricted ingredients; formulations; processing schedules; equipment and records; and processing controls of cured, dried, and cooked products. The controls also include the implementation of HACCP systems in all establishments and implementation of a generic *E. coli* testing program in slaughter establishments. Deficiencies are discussed below.

- In one out of six slaughter establishments, hogs were not stunned in such a manner that they would be rendered unconscious with a minimum excitement and discomfort such as a few hogs were observed staggering and crawling on the top of other stunned hogs and their throats were slit by the employee without any further stunning. *This is a repeat deficiency from the May 2001 audit.*

HACCP Implementation: All establishments approved to export meat products to the U.S. are required to have developed and implemented a HACCP system. Each of these systems was evaluated according to the criteria employed in the U.S domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were reviewed during the on-site audits of the 40 establishments. The auditors found the following deviations from FSIS' regulatory requirements.

- In 14 establishments, the HACCP plan was not validated to determine if it was functioning as intended. *In six of 14 establishments, this is a repeat deficiency.*

- In 20 establishments, the HACCP plan did not state adequately the procedures that the establishment would use to verify that the plan was being effectively implemented and the frequencies with which these procedures would be performed. The ongoing verification activities of the HACCP program were not performed adequately either by the establishment personnel or by the GOI meat inspection officials. *In 10 of 20 establishments, this is a repeat deficiency.*

- In 13 establishments, the HACCP plan did not address adequately the corrective actions to be followed in response to deviations from critical limits. *In six of 13 establishments, this is a repeat deficiency.*

- In 12 establishments, the hazard analysis was not adequately conducted. *In one of 12 establishments, this is a repeat deficiency.*

- In 12 establishments, the HACCP plan did not adequately specify critical limits for each CCP and the frequency with which these procedures would be performed. *In four of 12 establishments, this is a repeat deficiency.*

- In six establishments, the HACCP plan flow chart did not adequately describe the process steps and product flow.

- In six establishments, the HACCP plan's record keeping system was not adequately documenting the monitoring of CCPs. *In two of six establishments, this is a repeat deficiency.*

- In three establishments, there was no adequate written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur. *In one of three establishments, this is a repeat deficiency.*

- In four establishments, the HACCP plan did not address the intended use of or the consumers of the finished product(s). *In one of four establishments, this is a repeat deficiency.*

- In three establishments, the final review of all documentation associated with the production of the product prior to shipping was not done. *In one of three establishments, this is a repeat deficiency.*

Testing for Generic *E. coli*

Italy has adopted the FSIS regulatory requirements for generic *E. coli* testing. Six of the 40 establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing. These six establishments were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The following deficiencies were noted.

- In three establishments, the carcass selection was not made randomly and use of a random method of selection was not specified in the procedure. *In three of three establishments, this is a repeat deficiency.*
- In two establishments, the sequence of carcass sponging was not being followed properly. *In two of two establishments, this is a repeat deficiency.*
- In one establishment, the procedure did not designate the employee(s) responsible for collecting the samples.

ENFORCEMENT CONTROLS

The fifth of the five risk areas that the auditor reviews is Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella* species.

Except as noted in this report, the GOI had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the U.S. with product intended for the domestic market.

In addition, controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other counties for further processing. Adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* Species

Prior to this audit Italy had advised FSIS that it had adopted all of the FSIS requirements for *Salmonella* species testing with the sole exception of the use of different analytic methods. FSIS had determined that Italy's use of the ISO 6579 and AOAC 967.25 methods were equivalent to FSIS' requirements.

Six of the establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

The following deficiencies were noted.

- In all six slaughter establishments, *Salmonella* samples were collected by the establishment personnel under the direct supervision of government employees. The only

scenario currently approved by FSIS for Italy is the use of government employees to collect samples. *In six of six establishments, this is a repeat deficiency.*

- In two establishments, the samples were not being taken randomly.

- In two establishments, the sequence of carcass sponging was not being followed properly. *In two of two establishments, this is a repeat deficiency.*

- Microbiology methods in-use tended to be based on standard methods. However, some laboratories are modifying standard methods and are not strictly adhering to standard protocols. Modifications to standard methods are not acceptable. *This is a repeat deficiency from the May 2001 audit.*

Species Verification Testing

At the time of this audit, Italy was required to test product for species verification. Species verification testing was not being conducted in eight establishments (5L, 41L, 92M/S, 160L, 205L, 335L, 363L, and 989L). Species testing is required in any establishment that is approved to ship product to the U.S. This testing is required on products that are not readily identifiable as to source (i.e., any product that does not consist of a whole, intact muscle such as cooked sausage product or chopped and formed ham product).

Listeria monocytogenes Testing

Establishments producing ready-to-eat products are required to reassess their HACCP plans to determine if *Listeria monocytogenes* should be considered as a hazard reasonably likely to occur. All 34 processing establishments that were reviewed on-site produce ready-to-eat products and had not amended their HACCP plans to include *Listeria monocytogenes* as a hazard reasonably likely to occur.

Monthly Reviews

The internal review program was applied equally to both export and non-export establishments. Internal review visits were both announced and not announced in advance, and were conducted, at times by individuals and at other times by a team of reviewers. These reviews were being performed by the regional or local officials, and were all veterinarians. The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in the regional and provincial offices.

In some establishments, only two or three reviews are conducted each year instead of monthly as required by FSIS. However, as stated earlier, the MOH has pledged to acquire the staff and resources to begin conducting monthly reviews of all certified establishments.

Inspection System Controls

The following deficiencies were noted.

- In eight establishments, periodic supervisory visits were not performed monthly. Only two to four internal reviews were conducted per year by the local officials and/or by the veterinarian assigned to different establishments in the same area. *This is a repeat deficiency from the May 2001 audit.*

- In 11 establishments, edible and inedible product containers were not identified to prevent possible cross-contamination/cross-utilization in the boning room, ham-slicing rooms, ham salting rooms, and processing rooms. *In two of 11 establishments, this is a repeat deficiency from the May 2001 audit.*

- In two establishments, incorrect labels were used. For example, in one establishment a statement on the label of Leonardo Ham declares that the hams used are from Italy, when the hams were actually imported from Denmark. In another establishment, the label approval indicates the European Union number instead of one approved for the U.S.

Exit Meeting

The exit meeting was conducted at the Ministry of Health in Rome, on December 19, 2001. The participants from Italy were Dr. Silvio Borrello, Dirigente II Livello- Direttore Ufficio VIII, Department of Food Nutrizion and Public Veterinary Health (DANSPV); Dr. Pietro Noe, Veterinario Dirigente I Livello-Ufficio VIII; Dr. Angelo Di Donato, Veterinario Dirigente I Livello, Ufficio III; Dr. Alessandra Di Sandro, Veterinario Dirigente I Livello, Ufficio VIII; Dr. Alessandro Cascone, Veterinario Dirigente I Livello, Ufficio VIII; Dr. Lidia Cecio, Veterinario Dirigente I Livello, Ufficio VIII; Dr. Raffaella Augelli, Veterinario Coadiutore Ufficio VIII; Dr. Ornella Pinto, Veterinario Dirigente I Livello, Ufficio VIII; Dr. Pierantoni Marco, Assessorato Alla Sanita, Regione Emilia Romagna; Dr. Duratti Giuseppe, Assessorato Alla Sanita, Regione Friuli Venezia Giulia; Dr. Sigismondi Mariano, Assessorato Alla Sanita, Regione Lazio; Dr. Giorgioni Adriano, Assessorato Alla Sanita, Regione Lazio; Dr. Clare Norman, Assessorato Alla Sanita, Regione Lazio; Dr. Filippo Castoldi, Assessorato Alla Sanita, Regione Lombardia; Dr. Guglielmo D' Aurizio, Assessorato Alla Sanita, Regione Marche; Dr. Baronti Omelio, Assessorato Alla Sanita, Regione Toscana; Dr. Riccardo Galesso, Assessorato Alla Sanita, Regione Veneto; Dr. Migrelli Arrigo, Istituto Zooprofilattico Della Lombardia E Dell' Emilia; Dr. Silvamo Moca, Istituto Zooprofilattico Dell' Umbria E Delle Marche; Dr. Decastelli Lucia, Istituto Zooprofilattico Del Piemonte Della Liguria E Della Valle D' Aosta and Ms. Marina Paluzzi, Interpreter.

The United States government participants were Dr. Faizur R. Choudry, International Audit Staff Officer, TSC, FSIS; Dr. Oto Urban, International Audit Staff Officer, TSC, FSIS;

Dr. Ghias Mughal, Branch Chief, International Review Staff, FSIS; Ms. Ann Murphy, Agricultural Attaché, United States Embassy, Rome, and Mr. Franco Regini, Agricultural Specialist, Foreign Agricultural Service, United States Embassy, Rome.

The auditor explained to the GOI inspection officials that their inspection system was audited in accordance with the European Union/United States Veterinary Equivalence Agreement (Agreement). The auditors audited the meat inspection system against European Commission Directives, specifically (1) Council Directive 64/433/EEC of June 1964, (2) Council Directive 96/23/EC of April 29, 1996, and (3) Council Directive 96/22/EC of April 29, 1996. These three directives have been declared equivalent under the Agreement. In areas not covered by these directives, such as the requirement for daily inspection in processing establishments, the requirement for humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, and the requirement for species verification testing, the auditors audited against FSIS requirements and equivalence determinations, including the Pathogen Reduction/HACCP requirements. These requirements include regulations on HACCP, SSOP, and *E. coli* and *Salmonella* testing.

The following topics were discussed:

1. The lack of daily inspection coverage in establishments producing products for export to the U.S.
2. Inadequate inspection system controls, including the denaturing of condemned or inedible products, enforcement of humane slaughter laws, use of inspection procedures to check for disease, and carcass and offal inspection requirements.
3. Instances of actual product contamination and instances of the potential for direct product contamination.
4. The lack of monthly supervisory reviews of most certified establishments.
5. The continuing problems with the implementation and maintenance of SSOP in certified establishments.
6. The continuing problems with implementation and maintenance of HACCP systems in certified establishments.
7. Deficiencies in the *Salmonella* sampling and testing program.
8. Deficiencies in Italy's microbiological laboratory testing programs.
9. The lack of testing for species verification.
10. Deficiencies in the Instituti Zooproficlattici Sperimentali residue laboratories in Torino and Brescia concerning the laboratories' quality assurance programs.
11. The supervisory structure above the level of official veterinarian in the establishment is weak at best.

Ministry of Health officials stated that they would take the necessary steps to ensure that corrective actions and preventive measures are taken to address the noted deficiencies.

CONCLUSION

The Italian meat inspection system has major deficiencies, which demonstrate a lack of government oversight as evidenced by the findings presented in the report. However, a few improvements were observed in individual establishments' HACCP and SSOP programs.

The auditors found sanitation and other conditions to be so serious in four establishments that the establishments were delisted by the GOI. The auditors found significant problems in five establishments, which were then designated as marginal/re-review.

The GOI meat inspection officials stated that they would ensure prompt compliance. However, these assurances have been given previously at the conclusion of the May 2001 and September 2000 audits yet few, if any, corrective actions have been taken to date.

Dr. Faizur R. Choudry
International Audit Staff Officer

(signed)Dr. Faizur R. Choudry

ATTACHMENTS

A. Data Collection Instrument for SSOP
B. Data Collection Instrument for HACCP Programs
C. Data Collection Instrument for Generic *E. coli* testing.
D. Data Collection Instrument for *Salmonella* Testing
E. Laboratory Audit Forms
F. Individual Foreign Establishment Audit Forms
G. Written Foreign Country's Response to the Draft Final Audit Report *(no comments received)*

Attachment A

Data Collection Instrument for SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows: (see next page)

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Respons-ible indiv. Identified	7. Docu-mentation done daily	8. Dated and signed
5-L	√	√	√	√	√	√	√	√
23-L	√	√	√	√	√	√	√	√
25-L	√	√	√	√	√	√	√	√
41-L	√	√	√	√	√	√	no	√
90-L	√	√	√	√	√	√	no	√
92 M/S	√	√	√	√	√	√	√	√
151-L	√	√	√	√	√	√	√	√
160-L	√	√	√	√	√	√	√	√
172-L	√	no	√	√	√	√	no	√
205-L	√	√	√	√	√	√	√	√
272 M/S	√	√	√	√	√	√	√	√
304 M/S	√	√	√	√	√	√	√	√
312 M/S	√	√	√	√	√	√	√	√
316-L	√	√	√	√	√	√	√	√
335-L	√	√	√	√	√	√	√	√
363-L	√	no	no	√	√	√	√	√
368-L	√	√	no	√	√	√	√	√
442-L	√	√	√	√	√	√	√	√
476-L	√	√	√	no	√	√	no	√
480-L	√	√	√	√	√	√	no	√
492-L	√	√	√	√	√	√	no	√
500-L	√	√	√	√	√	√	no	√
513-L	√	√	√	√	√	√	√	√
514-L	√	√	√	√	√	√	√	√
550-L	√	√	√	√	√	√	√	√
586-L	√	√	√	√	√	√	√	√
632-L	√	√	√	√	√	√	√	√
643 M/S	√	√	√	√	√	√	√	√
649-L	√	√	√	√	√	√	no	√
683-L	√	√	√	√	√	√	no	√
688-L	√	√	√	√	√	√	√	√
714-L	√	√	√	√	√	√	√	√
720-L	√	√	√	√	√	no	√	√
744-L	√	√	√	√	√	√	no	√
758-L	√	√	√	√	√	√	√	√
791 M/S	√	√	√	√	√	√	√	√
989-L	√	√	no	√	√	no	no	√
1170-L	√	√	√	√	√	√	no	√
1217-L	√	√	√	√	√	√	√	√
1223-L	√	√	√	√	√	√	√	√

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis and Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing routine pre-shipment document reviews.

The results of these evaluations were as follows: (see next page)

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. Use & users included	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is specified	7. Corr. Actions are described	8. Plan validated	9. Adequate verific. procedures	10.Adequate documentation	11. Dated and signed	12.Preshipmt. doc. review
5-l	no	√	√	√	√	no	√	√	√	no	√	√
23-l	√	√	√	√	√	√	no	√	√	√	√	√
25-l	√	√	√	√	√	√	√	√	√	√	√	√
41-l	√	no	√	√	√	no	√	√	no	√	√	√
90-l	√	√	no	√	√	√	√	√	√	√	√	√
92ms	√	√	√	√	√	√	√	no	no	√	√	√
151-l	√	√	√	√	√	√	√	√	√	√	√	√
160-l	√	√	√	√	√	no	no	no	no	no	√	no
172-l	no	no	√	√	√	no	no	no	no	no	√	√
205-l	√	√	√	√	√	√	√	no	no	√	√	√
272ms	√	√	√	√	√	√	√	√	no	√	√	√
304ms	√	√	√	√	√	√	no	no	no	√	√	√
312ms	no	no	√	√	√	no	no	√	no	√	√	√
316-l	√	√	√	√	√	√	√	√	√	√	√	√
335-l	no	√	√	√	√	no	√	no	no	√	√	√
363-l	√	no	√	no	√	no	√	no	no	√	√	no
368-l	√	√	√	√	√	no	no	√	no	√	√	√
442-l	√	no	√	√	√	√	no	no	no	no	√	√
476-l	√	no	√	√	√	√	√	√	√	√	√	√
480-l	√	no	√	√	√	√	no	√	no	√	√	√
492-l	√	√	√	√	√	√	√	√	√	√	√	√
500-l	no	no	no	√	√	no	no	no	no	no	√	√
513-l	√	√	√	√	√	√	√	√	√	√	√	√
514-l	√	√	√	√	√	√	√	√	√	√	√	√
550-l	√	no	√	no	√	√	√	no	√	√	√	√
586-l	no	no	√	√	√	√	√	√	no	√	√	√
632-l	√	√	√	√	√	√	√	√	√	√	√	√
643ms	√	√	√	√	√	no	no	no	no	√	√	√
649-l	√	√	√	√	√	no	no	√	√	√	√	√
683-l	√	√	√	√	√	√	√	√	√	√	√	√
688-l	√	√	√	√	√	√	√	√	√	√	√	√
714-l	√	√	√	√	√	√	√	√	√	√	√	√
720-l	√	no	√	√	√	√	√	no	no	√	√	√
744-l	√	√	no	√	√	√	no	√	√	√	√	√
758-l	√	√	√	√	√	√	√	√	√	√	√	√
791ms	√	√	√	√	√	√	√	no	no	√	√	√
989-l	√	no	no	no	no	no	no	no	no	no	√	no
1170-l	√	√	√	√	√	√	√	√	√	√	√	√
1217-l	√	√	√	√	√	√	√	√	no	√	√	√
1223-l	√	√	√	√	√	√	√	√	√	√	√	√

Attachment C

Data Collection Instrument for Generic *E. coli* Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli.*
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
92 ms	√	√	√	√	√	√	√	√	√	√
272ms	√	√	√	√	√	no	no	√	√	√
304 ms	√	√	√	√	√	no	no	√	√	√
312 ms	√	√	√	√	√	√	√	√	√	√
643ms	√	no	√	√	√	√	no	√	√	√
791 ms	√	√	√	√	√	√	√	√	√	√

6. Sequence for hog carcass sample site was belly, ham, jowl instead of ham, belly, jowl.

Attachment D

Data Collection Instrument for *Salmonella* Testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. *Salmonella* testing is being done in this establishment.

2. Carcasses are being sampled.

3. Ground product is being sampled.

4. The samples are being taken randomly.

5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is being used for sampling.

6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	*1. Testing as required*	*2. Carcasses are sampled*	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
92 M/S	√	√	N/A	√	√	√
272 M/S	√	√	N/A	no	no	√
304 M/S	√	√	N/A	no	no	√
312 M/S	√	√	N/A	√	√	√
643 M/S	√	√	N/A	√	√	√
791 M/S	√	√	N/A	√	√	√

5. Sequence for hog carcass sample site was belly, ham, jowl instead of ham, belly, jowl.

NOTE: Establishment personnel were collecting the samples under the direct supervision of GOI inspection officials.

Attachment E

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: 11/29/01

NAME OF FOREIGN LABORATORY: ISTITUTI zooprofilattico Sezioni Diagnostiche

FOREIGN GOV'T AGENCY: Umbria - Marche Region

CITY & COUNTRY: ANCONA, Italy

ADDRESS OF LABORATORY: 60100 ANCONA via Cupa di Posatora

NAME OF REVIEWER: Ghias Mughal

NAME OF FOREIGN OFFICIAL: DR. Donatella Ottaviani

Residue Code/Name ▶

	REVIEW ITEMS	ITEM #	EVALUATION CODE	
SAMPLING PROCEDURES	Sample Handling	01		OK
	Sampling Frequency	02		NA
	Timely Analyses	03		OK
	Compositing Procedure	04		NA
	Interprat Comp Data	05		OK
	Data Reporting	06		OK
ANALYTICAL PROCEDURES	Acceptable Method	07		U: See attached Comments
	Correct Tissue(s)	08		NA
	Equipment Operation	09		OK
	Instrument Printouts	10		OK
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11		NA
	Recovery Frequency	12		NA
	Percent Recovery	13		NA
	Check Sample Frequency	14		OK
	All analyst w/Check Samples	15		OK
	Corrective Actions	16		OK
	International Check Samples	17		OK
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL CODE	
OTHER REVIEW		19	EVAL. CODE	
		20		

SIGNATURE OF REVIEWER

DATE

FSIS FORM 8620-4 (9/90)

Designed on PageMaker 6.0 for Windows

Laboratory: Istituti Zooprofilattico, Ancona

Address: Sezione Diagnostiche
60100 ANCONA
Via Cupa di Posatora, Italy

Date of Visit: 11/29/01

Reviewer: Dr. Ghias Mughal

Foreign Official: Dr. Donatella Ottaviani, Director, Food Microbiology

Findings: There was no US approved slaughter plant in the Region , however, there was an approved processing plant at the time of the visit . Samples from this plant are analyzed at this laboratory. All samples are given to the analyst are anonymous, therefore the analyst is unaware of the origin of the sample. Director said that laboratory will request the ASL to mark US samples in future and will use ISO methods for analysis of these samples.

Methodology used:

Listeria monocytogenes: Use a modification of ISO 11290-1 method, reference ISS procedure and ISTITAN 96/3. *This is a repeat finding*

Salmonella: Not strictly adhering to any single standard method, although reference ISO 6579, Italian Law and site the FDA Bacteriological Analytical Manual (BAM) verbally. ISO method used is modified and is certified by AFNOR. They run an immunoassay screen "FOSS EIA" that is AOAC-performance based.
This is a repeat finding.

Generic *E. coli*: Use Biomerieux"Coli-ID" mrthod which has been validated by AFNOR. *This is a repeat finding.*

Use of Control Organisms: Do not routinely run known bacterial control organisms concurrently with batches of samples to validate test runs. They will soon start this check sample program. *This is a repeat finding*

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE	NAME OF FOREIGN LABORATORY
11/30/01	Istituto Superiore di Sanita (ISS) Viale Regia Elena 299

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Lazio Region	Rome, Italy	00161, Rome

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
DR. Ghias Mughal	DR. Paolo Aureli Director Food Microbiology

Residue Code/Name ▶

	REVIEW ITEMS	ITEM #	EVALUATION CODE														
SAMPLING PROCEDURES	Sample Handling	01		OK													
	Sampling Frequency	02		NA													
	Timely Analyses	03		OK													
	Compositing Procedure	04		NA													
	Interprat Comp Data	05		OK													
	Data Reporting	06		OK													
ANALYTICAL PROCEDURES	Acceptable Method	07		U	See attached Comments												
	Correct Tissue(s)	08		NA													
	Equipment Operation	09		OK													
	Instrument Printouts	10		OK													
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11		NA													
	Recovery Frequency	12		NA													
	Percent Recovery	13		NA													
	Check Sample Frequency	14		U	See attached Comments												
	All analyst w/Check Samples	15		OK													
	Corrective Actions	16		OK													
	International Check Samples	17		OK													
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE														
OTHER REVIEW		19	EVAL. CODE														
		20	EVAL. CODE														

SIGNATURE OF REVIEWER

DATE

FSIS FORM 9620-4 (9/90)

Designed on PageMaker 6.0 Windows

Laboratory: Istituto Superioredi Sanita (ISS)

Address: Viale Regia Elena 299
00161, Rome, Italy

Date of Visit: 11/30/01

Reviewer: Dr.Ghias Mughal

Foreign Official: Dr. Paolo Aureli, Director, Food Microbiology

This institute serves as an authority and reference laboratory for all other Istituti Zooprofilattici.It is the technical and scientific body of the Italian National Health Service for matters relating public health and is responsible for public health research experiments, and training.
ISS does not test product samples from any US approved plants.

Methodology used :

Salmonella: Use National Italian method UNI EN 12824

Generic *E. Coli*: Use National Italian Method U59132360 (MPN method using modified laurel-sulfate tryptose broth with MUG)

Listeria monocytogenes: Use ISO method# 11290-1

Use of Control Organisms: Do not routinely run known bacterial control organisms concurrently with batches of samples to validate test runs.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: 12/3/01

NAME OF FOREIGN LABORATORY: Istituto Zooprofilattico Via Castelpulci

FOREIGN GOV'T AGENCY: Lazio - Toscana Regions

CITY & COUNTRY: Florence, Italy

ADDRESS OF LABORATORY: 50010 SanMartino alla Palma

NAME OF REVIEWER: DR. Ghias Mughal

NAME OF FOREIGN OFFICIAL: DR. Paolo Marconi

	REVIEW ITEMS	ITEM #	EVALUATION CODE	Residue Code/Name ▶											
SAMPLING PROCEDURES	Sample Handling	01		OK											
	Sampling Frequency	02		NA											
	Timely Analyses	03		OK											
	Compositing Procedure	04		NA											
	Interprat Comp Data	05		OK											
	Data Reporting	06		OK											
ANALYTICAL PROCEDURES	Acceptable Method	07		U	See attached Comments										
	Correct Tissue(s)	08		NA											
	Equipment Operation	09		OK											
	Instrument Printouts	10		OK											
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11		NA											
	Recovery Frequency	12		NA											
	Percent Recovery	13		NA											
	Check Sample Frequency	14			See Attached Comments										
	All analyst w/Check Samples	15		OK											
	Corrective Actions	16		OK											
	International Check Samples	17		OK											
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL CODE												
OTHER REVIEW		19	EVAL. CODE												
		20													

SIGNATURE OF REVIEWER

DATE

FSIS FORM 9820-4 (9/90)

Laboratory: Istituto Zooprofilattico

Address: Via Castelpulci
50010 Sanmartino allaPalma
Florence, Italy

Date of Visit: 12/3/01

Reviewer: Dr. Ghias Mughal

Foreign Official: Dr. Paola Marconi, Director, Food Microbiology

There is no US approved slaughter house in the area. However, there are some processed product establishments near by. Laboratory is not aware if samples are from US certified plants. Laboratory has been accredited by SINAL and have one external audit annually.

Methodology used :

Listeria monocytogenes: Use a modification of ISO method # 11290-1. *This was a repeat finding.*

Salmonella: Previously they were using ISO method # 6579 which has been modified. Laboratory conserves agar plates by streaking secondary enrichment to only one half of the agar plate, rather than using a whole plate for each secondary enrichment broth culture. Appears to have been *corrected.*

Generic *E. Coli*: Use Biomeriux "Coli ID" method which has been validated by AFNOR.

Use of Control Organisms: There has been improvement in this area since last audit. They have started using control organisms with some batches. Also, improvement was observed in the check sample program.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: 12/4/01

NAME OF FOREIGN LABORATORY: Istituto Zooprofilattico Sede Centrale 0610 Perugia

FOREIGN GOV'T AGENCY: Umbria-Marche Region

CITY & COUNTRY: Perugia Italy

ADDRESS OF LABORATORY: Via G. Salvemini

NAME OF REVIEWER: DR. Ghias Mughal

NAME OF FOREIGN OFFICIAL: DR. Moca Silvano, Director Quality Control

Residue Code/Name ▶

	REVIEW ITEMS	ITEM #	EVALUATION CODE
SAMPLING PROCEDURES	Sample Handling	01	OK
	Sampling Frequency	02	NA
	Timely Analyses	03	OK
	Compositing Procedure	04	NA
	Interprat Comp Data	05	OK
	Data Reporting	06	OK
ANALYTICAL PROCEDURES	Acceptable Method	07	U* See attached Comments
	Correct Tissue(s)	08	NA
	Equipment Operation	09	OK
	Instrument Printouts	10	OK
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	NA
	Recovery Frequency	12	NA
	Percent Recovery	13	NA
	Check Sample Frequency	14	See attached Comments
	All analyst w/Check Samples	15	OK
	Corrective Actions	16	OK
	International Check Samples	17	OK
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL CODE
OTHER REVIEW		19	EVAL. CODE
		20	EVAL. CODE

SIGNATURE OF REVIEWER

DATE

Laboratory: Istituto Zooprofilattico, Perugia
Address: Sede Centrale
0610 Perugia
Via G. Salvemini, Perugia Italy

Date of Visit: 12/4/01

Reviewer: Dr.Ghias Mughal

Foreign Official: Dr. Moca Silvano , Director, Quality Control

There is no US approved slaughter house in the area. However, there are some processed products establishments near by. Laboratory processes samples from US certified plants. Laboratory.

Accreditation: SINAL, have one external audit annually.

Methodology used: : Testing procedures for *Listeria monocytogenes, salmonella,* and generic *E. coli* is similar to the Institute in Ancona.

Listeria monocytogenes: Use a modification of ISO method # 11290-1 in combination with a VIDAS ELISA screening test.

Salmonella: Using ISO method # 6579 in combination with VIDAS ELISA screening test. This method has an AFNOR validation, however, it is not used at FSIS laboratories.

Generic *E. Coli*: Use Biomeriux "Coli ID" method which has been validated by AFNOR.
All of the above are repeat findings. Director of Quality Control Program indicated that he has no problem using methods acceptable to FSIS but he needs instructions from the Ministry of Health to do so.

Use of Control Organisms: Do not routinely run known bacterial control organisms concurrently with batches of samples to validate test runs.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: 12/5/01

NAME OF FOREIGN LABORATORY: Istituto Zooprofilattico
ADDRESS OF LABORATORY: Via E Diena 16, 41100 Modena

FOREIGN GOV'T AGENCY: Lombardia - Emelia Romagna Regions
CITY & COUNTRY: Modena, Italy

NAME OF REVIEWER: DR. Ghias Mughal
NAME OF FOREIGN OFFICIAL: DR. Stefano Bassi, Director

Residue Code/Name ▶

	REVIEW ITEMS	ITEM #	EVALUATION CODE	
SAMPLING PROCEDURES	Sample Handling	01		OK
	Sampling Frequency	02		NA
	Timely Analyses	03		OK
	Compositing Procedure	04		NA
	Interprat Comp Data	05		OK
	Data Reporting	06		OK
ANALYTICAL PROCEDURES	Acceptable Method	07		U See Attached Comments
	Correct Tissue(s)	08		NA
	Equipment Operation	09		OK
	Instrument Printouts	10		OK
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11		NA
	Recovery Frequency	12		NA
	Percent Recovery	13		NA
	Check Sample Frequency	14		U See attached Comments
	All analyst w/Check Samples	15		OK
	Corrective Actions	16		OK
	International Check Samples	17		OK
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	
OTHER REVIEW		19	EVAL. CODE	
		20		

SIGNATURE OF REVIEWER

DATE

FSIS FORM 9820-4 (9/90)

Laboratory: Istituto Zooprofilattico, Modena
Address: Via E. Diena 16
41100 Modena, Italy

Date of Visit: 12/5/01

Reviewer: Dr.Ghias Mughal

Foreign Official: Dr. Stefano Bassi, Director.

Receives samples from US approved slaughter and processing plants. Samples are brought to the laboratory by employees of ASL in automobiles, are coded in the receiving area and sent to the technician as anonymous samples. This is normal procedure in all of the Italian government laboratories.
Laboratory has been accredited by SINAL in May 2001.

Methodology used:

Listeria monocytogenes: Use an internally done modification of ISO method # 11290-1.

Salmonella: Using ISO method # 6579 which has been internally modified.

Generic *E. Coli*: Previously were using a modification of AOAC-ISO method # 991-14. Seems to have recently started using this ISO method without modification.

Use of Control Organisms: Do not routinely run known bacterial control organisms concurrently with batches of samples to validate test runs.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: 12/7/01

NAME OF FOREIGN LABORATORY: Istituto Zooprofilattico Strada Circonvallazione Sud 21/A

FOREIGN GOV'T AGENCY: Lombardia - Emelia Romagna Regions

CITY & COUNTRY: Montova, Italy

ADDRESS OF LABORATORY: 46100 Montova

Società Cooperativa
IC SATORIO
Via Roma, n. 148
Tel. [illegible] - Fax 348777/0
Direttore: Prof. CANCRINI CORTELLEZZI
Carlo

NAME OF REVIEWER: DR. Ghias Mughal

NAME OF FOREIGN OFFICIAL: DR. Carlo Rosignoli, Director General

Residue Code/Name ▶

	REVIEW ITEMS	ITEM #	EVALUATION CODE															
SAMPLING PROCEDURES	Sample Handling	01		OK														
	Sampling Frequency	02		NA														
	Timely Analyses	03		OK														
	Compositing Procedure	04		NA														
	Interprat Comp Data	05		OK														
	Data Reporting	06		OK														
ANALYTICAL PROCEDURES	Acceptable Method	07		U			See Attached Comments											
	Correct Tissue(s)	08		NA														
	Equipment Operation	09		OK														
	Instrument Printouts	10		OK														
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11		NA														
	Recovery Frequency	12		NA														
	Percent Recovery	13		NA														
	Check Sample Frequency	14					See Attached Comments											
	All analyst w/Check Samples	15		OK														
	Corrective Actions	16		OK														
	International Check Samples	17		OK														
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE															
OTHER REVIEW		19	EVAL. CODE															
		20																

SIGNATURE OF REVIEWER

DATE

FSIS FORM 9620-4 (9/90)

Designed on PageMaker 6.0 Windows

Laboratory: Istituto Zooprofilattico, Montova
Address: Strada Circonvallazione Sud 21/A
46100 Montova, Italy

Date of Visit: 12/7/01

Reviewer: Dr.Ghias Mughal

Foreign Official: Dr. Carlo Rosignoli, Director General.

Receives samples from US approved slaughter and processing plants. Samples are brought to the laboratory by employees of ASL in automobiles, are coded in the receiving area and sent to the technician as anonymous samples. This is normal procedure in all of the Italian government laboratories.
Laboratory has been accredited by SINAL.

Methodology used:

Listeria monocytogenes: Use an internally done modification of ISO method # 11290-1.

Salmonella: Using ISO method # 6579 which has been internally modified.

Generic *E. Coli*: Use a modification of AOAC-ISO method # 991-14. Have recently started using this ISO method without modification.

Use of Control Organisms: Do not routinely run known bacterial control organisms concurrently with batches of samples to validate test runs.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: 12/12/01

NAME OF FOREIGN LABORATORY: Istituto Zooprofilattico Sede Centrale 10154 Torino

FOREIGN GOV'T AGENCY: Piemonte - Liguria Region

CITY & COUNTRY: Torino, Italy

ADDRESS OF LABORATORY: Via Bologna 148

Sede Centrale
10154 TORINO
Via Bologna 148
Tel. 011/26831 - Fax 248717/0
Direttore: Prof. CANCRINI CORTELLEZZI
GUIDO

NAME OF REVIEWER: DR. Ghias mughal

NAME OF FOREIGN OFFICIAL: DR. S. Andrvetto, Director General

Residue Code/Name ▶

	REVIEW ITEMS	ITEM #	EVALUATION CODE	
SAMPLING PROCEDURES	Sample Handling	01		OK
	Sampling Frequency	02		NA
	Timely Analyses	03		OK
	Composiding Procedure	04		NA
	Interprat Comp Data	05		OK
	Data Reporting	06		OK
ANALYTICAL PROCEDURES	Acceptable Method	07		cr : See attached Comments
	Correct Tissue(s)	08		NA
	Equipment Operation	09		OK
	Instrument Printouts	10		OK
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11		NA
	Recovery Frequency	12		NA
	Percent Recovery	13		NA
	Check Sample Frequency	14		U See Attached Comments
	All analyst w/Check Samples	15		OK
	Corrective Actions	16		OK
	International Check Samples	17		OK
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL CODE	
OTHER REVIEW		19	EVAL. CODE	
		20		

SIGNATURE OF REVIEWER

DATE

FSIS FORM 8820-4 (9/90)

See reverse for Definitions

Laboratory: Istituto Zooprofilattico, Torino
Address: Sede Centrale
10154 Torino,
Via Bologna 148, Italy

Date of Visit: 12/12/01

Reviewer: Dr. Ghias Mughal

Foreign Official: Dr. S. Andrvetto, Director General.

Receives samples from US approved slaughter and processing plants. Samples are brought to the laboratory by employees of ASL in automobiles, are coded in the receiving area and sent to the technician as anonymous samples. This is normal procedure in all of the Italian government laboratories.
Laboratory has been accredited by SINAL.

Methodology Used:

Listeria monocytogenes: Use AFNOR method V08-055 which appears to be similar to ISO method # 11290-1.

Salmonella: Using AFNOR method V08-052 which appears to be similar ISO method # 6579. Also use a ELISA VIDAS screening method.

Generic *E. Coli*: Use a draft ISO method which will become a standard Italian method (Italian UNI) in 2002.
Director of the laboratoryindicated that she has no problem using methods acceptable to FSIS but he needs instructions from the Ministry of Health to do so.

Use of Control Organisms. Do not routinely run known bacterial control organisms concurrently with batches of samples to validate test runs.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: 12/13/01

NAME OF FOREIGN LABORATORY: Istituto Zooprofilattico sede Centrale 25124 BRESCIA

FOREIGN GOV'T AGENCY: Lombardia – Emelia Romagna Regions

CITY & COUNTRY: Brescia, Italy

ADDRESS OF LABORATORY: Via A. Bianchi 7

NAME OF REVIEWER: DR. Ghias Mughal

NAME OF FOREIGN OFFICIAL: Proff. Lodetti Ezio Director General

Residue Code/Name ▶

	REVIEW ITEMS	ITEM #	EVALUATION CODE														
SAMPLING PROCEDURES	Sample Handling	01	OK														
	Sampling Frequency	02	NA														
	Timely Analyses	03	OK														
	Compositing Procedure	04	NA														
	Interprat Comp Data	05	OK														
	Data Reporting	06	OK														
ANALYTICAL PROCEDURES	Acceptable Method	07	U	See Attached Comments													
	Correct Tissue(s)	08	NA														
	Equipment Operation	09	OK														
	Instrument Printouts	10	OK														
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	NA														
	Recovery Frequency	12	NA														
	Percent Recovery	13	NA														
	Check Sample Frequency	14	U	See Attached Comments													
	All analyst w/Check Samples	15	OK														
	Corrective Actions	16	OK														
	International Check Samples	17	OK														
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL CODE														
OTHER REVIEW		19	EVAL. CODE														
		20															

SIGNATURE OF REVIEWER

DATE

FSIS FORM 9620-4 (9/90)

Laboratory: Istituto Zooprofilattico, Brescia
Address: Sede Centrale
25124 Brescia,
Via A. Bianchi 7, Italy

Date of Visit: 12/13/01

Reviewer: Dr. Ghias Mughal

Foreign Official: Proff. Lodetti Ezio, Director General.

There are US approved slaughter and processing plants in the area but the Quality Control Manager said they do not routinely run samples from US Plants . Most of these samples are processed at the Montova and Cremona laoratories. Samples are brought to the laboratory by employees of ASL in automobiles, are coded in the receiving area and sent to the technician as anonymous samples. This is normal procedure in all of the Italian government laboratories.
Laboratory has been accredited by SINAL.

Methodology used:.

Listeria monocytogenes: Use an inhouse modification of an ISO method which had been validated internally. *This is a repeat finding*

Salmonella: Using a modification of ISO method # 6579 which has been internally validated. *This is a repeat finding*

Generic *E. Coli*: Use an internally developed method . *Repeat finding.*

None of these methods have been sent to FSIS for equivalent determination.

Use of Control Organisms: Do not routinely run known bacterial control organisms concurrently with batches of samples to validate test runs.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: 12/17/01

NAME OF FOREIGN LABORATORY: Istituto Zooprofilattico Sede Centrale 00178 CAPANALLE (Roma)

FOREIGN GOV'T AGENCY: Lazio Region

CITY & COUNTRY: Rome Italy

ADDRESS OF LABORATORY: Via Appia Nuova 1411

NAME OF REVIEWER: DR. Ghias Mughal

NAME OF FOREIGN OFFICIAL: DR. Nazareno Brizioli, Director General

	REVIEW ITEMS	ITEM #	EVALUATION CODE	Residue Code/Name ▶											
SAMPLING PROCEDURES	Sample Handling	01		ok											
	Sampling Frequency	02		NA											
	Timely Analyses	03		ok											
	Compositing Procedure	04		NA											
	Interprat Comp Data	05		ok											
	Data Reporting	06		ok											
ANALYTICAL PROCEDURES	Acceptable Method	07		U											
	Correct Tissue(s)	08		NA											
	Equipment Operation	09		ok											
	Instrument Printouts	10		ok											
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11		U	See Attached Comments										
	Recovery Frequency	12		NA											
	Percent Recovery	13		NA											
	Check Sample Frequency	14		ok											
	All analyst w/Check Samples	15		ok											
	Corrective Actions	16		ok											
	International Check Samples	17		ok											
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL CODE												
OTHER REVIEW		19	EVAL. CODE												
		20	EVAL. CODE												

SIGNATURE OF REVIEWER

DATE

FSIS FORM 9820-4 (9/90)

Laboratory: Istituto Zooprofilattico, Rome
Address: Sede Centrale
00178 CAPANNELLE (Roma),
Via Appia Nuova 1411, Italy

Date of Visit: 12/17/01

Reviewer: Dr.Ghias Mughal

Foreign Official: Dott. Nazareno Brizioli Director General.

This laboratory analyses samples from plants approved for export to US. Generally samples are anonymous, however, some times they are marked as "USA-plant"

Laboratory has been accredited by SINAL, have one external audit annually.

Methodolgy Used:

Listeria monocytogenes: Use EN method 45001 at present but will change to IEC 17025 in near future . Will validate this mehtod and sent to FSIS for equivalence determination.

Salmonella: Use ISO method # 6579.

Generic *E. Coli*: Use AFNOR "coli ID milieu" method.

Director of Quality Control Program indicated that he has no problem using methods acceptable to FSIS but he needs instructions from the Ministry of Health to do so.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
11/29/01	Est. 5-L Levoni S.P.A.	Castelluchhio
		COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Castoldi and Dr. Minelli	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 O	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76 U
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 U
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	82 M
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	11/29/01	Est. 5-L Levoni S.P.A.	Castelluchhio
			COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Castoldi and Dr. Minelli	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

COMMENTS:

43. Inedible product was not denatured/decharacterized or under security before shipping for rendering.

76. A The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.
B. GOI meat inspection officials were not providing daily adequate inspection coverage. Inspector was visiting the establishment four times a week (the establishment operates five days per week) and the duration of visits was between one to three hours.

79. Species verification testing was not carried out as required by FSIS.

82. Establishment met FSIS basic regulatory requirements of HACCP program. The HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation: the flow diagram was not completed or did not include all process steps and product flow; there was not a critical limit and/or monitoring frequency for each CCP; and there were no records produced for monitoring of the HACCP plans CCPs, or the records did not show actual values and observations.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	
12-06-01	Est. 23-L Cesare Fiorucci S.P.A.	Langhirano
		COUNTRY: Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Dr. Cesare Allodi	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 M	Laboratory confirmation	57 A
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 N	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 O
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 O
Pest --no evidence	07 A	Operational sanitation	35 M	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 M	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 O
Equipment approval	16 O	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 M	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76 U
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 M	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 O
Personal dress and habits	25 A	Boneless meat reinspection	52 A	HACCP	82 M
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 O		

FOREIGN PLANT REVIEW FORM (reverse)	12-06-01	Est. 23-L Cesare Fiorucci S.P.A.	COUNTRY Italy
NAME OF REVIEWER Dr. Oto Urban	NAME OF FOREIGN OFFICIAL Dr. Cesare Allodi	EVALUATION [X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable	

COMMENTS:

12 There was not enough space for processing operation in the slicing room. The establishment has programmed the extension of this room in the near future.

19 Washed, clean trays were observed to contain some pieces of dry meat in the salting room. This deficiency was corrected immediately by the establishment management.

23 The street cloth and the working cloth of two employees were mixed together in one of the dressing room. This deficiency was corrected immediately by the establishment employee.

30 Product contacting the wall was observed in two of the drying rooms. This deficiency was corrected immediately by the establishment employee.

34, 35 The government inspector was performing pre-operational sanitation once or twice a year and operational sanitation twice a week.

43 The inedible product has not been denatured in this establishment.

76. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
12/07/01	Est. 25-L Tosini Pio SPA Industria Prosciutti	Langhirano
		COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Borrello & Dr. Lidia Cecio	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
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1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	02 O	Product reconditioning	31 M	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 A
Pest --no evidence	07 M	Operational sanitation	35 M	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 A
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 O	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76 U
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 (
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 ,
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 .
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	82 A
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	12/07/01	Est. 25-L Tosini Pio SPA Industria Prosciutti	Langhirano COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Borrello & Dr. Lidia Cecio	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

COMMENTS:

07. Gaps at the bottoms of the door to deboning room and raw ham receiving room were not sealed properly to prevent the entrance of rodents and other vermin. Establishment officials ordered correction.

31. Product that contacted the floor was not reconditioned in a sanitary manner before being added to the edible product and facility for reconditioning drop meat was inadequate such as designated area with adequate light. Establishment officials ordered correction immediately.

34, 35. GOI meat inspection officials were not adequately monitoring/verifying the adequacy and effectiveness of the pre-operational and operational sanitation SSOP. The daily pre-operational sanitation monitoring was performed once a year.

43. Inedible product was not denatured/decharacterized or under security before shipping for rendering.

76 A. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.
B. GOI meat inspection officials were not providing daily adequate inspection coverage. Inspector was visiting establishment once a week (the establishment operates five days a week). The duration of the visits was between one to two hours

NOTE: The deficiencies listed above were not identified by either establishment or inspection personnel. Corrective action was not initiated until the need was identified by the FSIS auditor.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
11/27/01	Est. 41-L Alcisa SPA	Zola Predosa (ER) COUNTRY: ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Pierantoni & Dr. Milane	[X] Acceptable [ ] Acceptable/Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
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1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 A
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 A
Pest --no evidence	07 M	Operational sanitation	35 M	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 O	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76 U
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 U
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 O	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	82 M
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	11/27/01	Est. 41-L Alcisa SPA	Zola Predosa (ER) COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Pierantoni & Dr. Milane	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

COMMENTS:

07. Gaps at the bottoms of emergency door leading to processing room were not sealed properly to prevent the entry of rodents and other vermin. Establishment officials ordered correction immediately.

34, 35 a) The pre-operational and operational sanitation monitoring deficiencies were not identified and any corrective/preventive measures taken were not documented by the establishment personnel. Establishment officials ordered correction immediately.
b) GOI meat inspection officials were not adequately monitoring/verifying the adequacy and effectiveness of the pre-operational sanitation SSOP. Inspector was performing pre-operational sanitation twice a month.

43. Inedible product was not denatured/decharacterized or under security before shipping for rendering.

76. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

79. Species verification testing was not carried out as required by FSIS.

82. Establishment met FSIS basic regulatory requirements of HACCP program. The HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation: the hazard analysis had not been conducted or was not complete; there was not a critical limit and/or monitoring frequency for each CCP; and the HACCP plan did not list the procedures to verify effective implementation and/or frequency of these procedures.

NOTE: The deficiencies listed above were not identified by either establishment or inspection personnel. Corrective action was not initiated until the need was identified by the FSIS auditor.

FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

11-21-01

Est. 90-L Greci E Folzani SPA

Feltno

COUNTRY
Italy

NAME OF REVIEWER
Dr. Oto Urban

NAME OF FOREIGN OFFICIAL
Dr. Allodi Cesare

EVALUATION
[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
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Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 M	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 O
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 O
Pest --no evidence	07 A	Operational sanitation	35 M	Processing records	63 O
Pest control program	08 M	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions – plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 O
Equipment approval	16 O	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
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Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	50 O	Imports	81 O
Personal dress and habits	25 M	Boneless meat reinspection	52 O	HACCP	82 M
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	Felino
	11-21-01	Est. 90-L Greci E Folzani SPA	COUNTRY Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Dr. Allodi Cesare	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

COMMENTS:

4 Waste receptacle cover is hand operated. Establishment will remove the cover from all waste receptacles.

8 Insectocuters were observed in all product processing/drying areas. Establishment officials will remove them from the product drying facilities.

25 One employee was observed with not completely covered street cloths. This deficiency was corrected by the establishment management.

34, 35 The SSOP pre-operational sanitation preventive action was missing. The official inspector was performing pre-operational and operational sanitation once or twice a week.

43 The inedible product was not denatured in this establishment.

76. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
11/19/01	Est. 92 M/S Fumagalli Industria Alimentare S.P.A.	Tavernerio
		COUNTRY: ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr.Gridavilla,Dr.Borrello,Dr.Castoldi,Dr.Cecio	[X] Acceptable [ ] Acceptable/Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
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1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
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Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
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(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 /
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Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY / COUNTRY
	11/19/01	Est. 92 M/S Fumagalli Industria Alimentare S.P.A.	CITY: Tavernerio COUNTRY: ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr.Gridavilla,Dr.Borrello,Dr.Castoldi,Dr.Cecio	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

COMMENTS:

19. Meat grinding equipment and band saw ready for use in the cold boning room were found with fat and pieces of meat from previous days' operation. Neither establishment nor GOI meat inspection officials took corrective action.

34, 35. GOI meat inspection officials were not adequately monitoring/verifying the adequacy and effectiveness of the pre-operational and operational sanitation SSOP. Inspector was performing pre-operational sanitation once a week.

41. Inspector was not incising and observing mandibular lymph nodes of hog heads. The mesenteric lymph nodes and spleen were not palpated as required in Council Directive 64/433/EEC of 26 June 1964. GOI meat inspection officials did not take any corrective actions.

43. Inedible product was not denatured/decharacterized or under security before shipping for rendering.

76. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

79. Species verification testing was not carried out as required by FSIS.

82. Establishment met FSIS basic regulatory requirements of HACCP program. The HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation: the HACCP plan had not been validated using multiple monitoring results; and the HACCP plan did not list the procedures to verify effective implementation and/or frequency of these procedures.

NOTE: The deficiencies listed above were not identified by either establishment or inspection personnel. Corrective action was not initiated until the need was identified by the FSIS auditor.

INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

12-07-01	Est. 151-L Leoncini Prosciutti S.P.A.	COUNTRY Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Dr. Visentini	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 M	Laboratory confirmation	57 A
Chlorination procedures	02 A	Product reconditioning	31 M	Label approvals	58 A
Back siphonage prevention	03 O	Product transportation	32 N	Special label claims	59 O
Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring	60 O
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 O
Pest --no evidence	07 A	Operational sanitation	35 M	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	2. DISEASE CONTROL		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 O
Equipment approval	16 O	Condemned product control	43 U	5. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	3. RESIDUE CONTROL		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76 U
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 O
Personal dress and habits	25 A	Boneless meat reinspection	52 A	HACCP	82 M
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 O		

FOREIGN PLANT REVIEW FORM (reverse)	12-07-01	Est. 151-L Leoncini Prosciutti S.P.A.	COUNTRY Italy
NAME OF REVIEWER Dr. Oto Urban	NAME OF FOREIGN OFFICIAL Dr. Visentini	EVALUATION [X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable	

COMMENTS:

3o Hair on several hams and product contacting walls in three cases were observed in three dryers. There was immediate corrective action taken by the establishment management.

31 There was no written program for handling of dropped product in this establishment. These deficiencies were scheduled for correction.

34, 35 The government inspector was performing pre-operational sanitation once a week and operational sanitation once a week.

43 No identification of inedible metal boxes were observed in the slicing room

76a The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

76b Internal reviews were performed only four times per year.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation. A clear description of the risk of one of the CCPs was missing; establishmment management agreed to re-write the section.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
11/20/01	Est. 160-L Raspini SPA	Piemonte
		COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Alberto Mancuso & Dr. Voghera, Vet. IIC	☐ Acceptable ☐ Acceptable/ Re-review ☒ Unacceptable

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(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
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Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 A
Pest --no evidence	07 U	Operational sanitation	35 M	Processing records	63 A
Pest control program	08 U	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 O	Export product identification	72 A
Over-product ceilings	17 U	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 M	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76 U
Dry storage areas	21 U	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 U
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 U
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 O	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	82 M
Personal hygiene practices	26 M	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	11/20/01	Est. 160-L Raspini SPA	Piemonte
			COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Alberto Mancuso & Dr. Voghera, Vet. IIC	☐ Acceptable ☐ Acceptable/ Re-review ☒ Unacceptable

COMMENTS:

7, 8, 21. The front and one side of dry storage room had no walls (partially protected with plastic curtains) to prevent the entry of rodents and other vermin. Mice droppings, wet floor with urine, cobwebs, dirt and debris were observed in the dry storage room and packaging materials were not stored on racks high enough to monitor pest control and sanitation programs. Evidence of rodent infestation was observed on December 20, 2000, January 5, and November 8, 2001, in the personnel offices and welfare rooms by the outside pest control company, during their routine monitoring program. Rodenticide was replaced in the bait boxes but no other effort was made to take corrective/preventive measures either by the pest control company/establishment personnel/GOI meat inspection officials.

17. Dripping condensate from overhead refrigeration units, rails, beams, and ceilings that were not cleaned/sanitized daily, was falling onto edible product that was exposed from broken packaged materials in the defrosting room. Neither establishment nor GOI meat inspection officials took corrective actions.

19. Flaking paint and rust was observed on working table and frame of working table in the processing room. Establishment officials ordered correction immediately.

26. Several employees were not observing good hygienic work habits to prevent direct product contamination such as: paper towels were kept under the cutting boards soaked with blood in the boning room; packaged edible product was not unpacked in a sanitary manner in the grinding room; employees' handling unclean trash container were also handling edible product without washing hands. Establishment officials took corrective actions in each case.

34, 35 A. The daily operational sanitation records did not reflect the actual sanitary conditions observed in the establishment.

B. GOI meat inspection officials were not adequately monitoring/verifying the adequacy and effectiveness of the pre-operational and operational sanitation SSOP. Inspector was performing pre-operational and operational sanitation two times a month.

43 A. Edible and inedible product containers were not identified to prevent cross contamination and/or cross utilization in the boning room. Establishment officials ordered correction immediately.

B. Inedible product was not denatured/decharacterized or under security before shipping for rendering.

76 A. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

B. GOI meat inspection officials were not providing daily adequate inspection covereage. Inspector was visiting the establishment three times a week (the establishment operates five days a week) and staying between one to three hours each visit.

79. Species verification testing was not carried out as required by FSIS.

80. Because of gross product contamination, inadequate pest control program, and lack of compliance of daily operational sanitation programs and procedures, inadequate inspectional controls, the status of this establishment is not equivalent to that required in the U.S programs. All the above deficiencies were discussed with Dr. Alberto Mancuso, Regional Veterinarian, and he agreed to remove Establishment 160-L from the list of establishments eligible to export meat and meat products to the United States, effective November 20, 2001.

82. Establishment met FSIS basic regulatory requirements of HACCP programs. The HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation: there was not a critical limit and/or monitoring frequency for each CCP; there was no description of corrective action to be taken when a critical limit was exceeded; the HACCP plan had not bee validated using multiple monitoring results; the HACCP plan did not list the procedures to verify effective implementation and/or frequency of these procedures; there were no records produced for monitoring of the HACCP plan CCPs, or the records did not show actual values and observations; and pre-shipment document reviews were not being conducted by establishment officials.

NOTE: The deficiencies listed above were not identified by either establishment or inspection personnel. Corrective action was not initiated until the need was identified by the FSIS auditor.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
12/13/01	Est. 172-L Unibon Salumi Soc. Coop. A.R.L.	Reggio Nell Emilia
		COUNTRY: ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Pierantoni, Dr. Noe, Dr. Lidia, Dr. Bergomi	☐ Acceptable ☒ Acceptable/ Re-review ☐ Unacceptable

CODES (Give an appropriate code for each review item listed below)
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1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
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Chlorination procedures	02 O	Product reconditioning	31 M	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 M	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 M	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 M	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76 U
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 (
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 /
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	82 M
Personal hygiene practices	26 M	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	12/13/01	Est. 172-L Unibon Salumi Soc. Coop. A.R.L.	Reggio Nell Emilia COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Pierantoni, Dr. Noe, Dr. Lidia,Dr. Bergomi	☐ Acceptable ☒ Acceptable/ Re-review ☐ Unacceptable

COMMENTS:

05. Two sanitizers were not maintained at the required temperature (82C) in the boning room. Establishment officials ordered correction immediately.

19. Fat scraps from previous operations were observed on nmerous ham racks for use in an equipment cleaning room. Neither establishment nor GOI meat inspection officials took corrective action.

26. An employee was not observing good hygienic work habits to prevent direct product contamination such as: he was observed handling containers for inedible product/dirty fork lift without washing hands, then handled edible product in the boning room. Establishment took corrective actions.

30. Hams were contacting dirty posts during transportation creating a potential for cross contamination in the boning room. Establishment officials ordered correction.

31. Product that contacted the floor was not reconditioned in a sanitary manner before being added to the edible product and facility for reconditioning drop meat was inadequate such as designated area with adequate light. Establishment officials ordered correction immediately.

34, 35 A. The daily pre-operational sanitation deficiencies were not identified and operational sanitation was not performed by the establishment personnel.
B. GOI meat inspection officials were not adequately monitoring/verifying the adequacy and effectiveness of the pre-operational and operational sanitation SSOP. Inspector was performing pre-operational and operational sanitation once a week. The establishment operated five days a week.

43 A. Edible and inedible product containers were not properly identified to prevent possible cross-contamination and/or cross utilization. Establishment officials ordered correction immediately.
B. Inedible product was not denatured/decharacterized or under security before shipping for rendering.

76. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

82. Establishment met FSIS basic regulatory requirements of HACCP program. The HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation: the flow diagram was not completed or did not include all process steps and product flow, the hazard analysis had not been conducted or was not complete, there was not a critical limit and/or monitoring frequency for each CCP, there was no description of corrective action to be taken when a critical limit was exceeded; the HACCP plan had not been validated using multiple monitoring results; the HACCP plan did not list the procedures to verify effective implementation and/or frequency of these procedures; and there were no records produced for monitoring of the HACCP plan CCPs, or the records did not show actual values and observations.

NOTE: The deficiencies listed above were not identified by either establishment or inspection personnel. Corrective action was not initiated until the need was identified by the FSIS auditor.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
12/03/01	Est. 205-L Principe Di San Daniele SPA	San Daniele D Fruili
		COUNTRY: ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Caliz, IIC; Dr. Renato Coassin, Reg. Dir.	[X] Acceptable [ ] Acceptable/Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
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Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81
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FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	12/03/01	Est. 205-L Principe Di San Daniele SPA	San Daniele D Fruili COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Caliz, IIC; Dr. Renato Coassin, Reg. Dir.	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

COMMENTS:

31. Product that contacted the floor was not reconditioned in a sanitary manner before being added to the edible product and facility for reconditioning drop meat was inadequate such as designated area with adequate light. Establishment officials ordered correction immedicately.

34, 35 A. GOI meat inspection officials were not providing adequate daily inspection covereage. Inspector was visiting establishment one to two times a week (the establishment worked five days per week). The duration of the visits was between one to two hours.
B. GOI meat inspection officials were not adequately monitoring/verifying the adequacy and effectiveness of the pre-operational and operational sanitation SSOP. The dialy pre-operational sanitation monitoring was performed one to two times a month.

43. Inedible product was not denatured/decharacterized or under security before shipping for rendering.

76 A. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.
B. The supervisory visits that were performed were not done monthly. Only four visits were conducted per year by the local distric/provincial officials.

79. Species verification was not carried out as required by FSIS.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation: the HACCP plan had not been validated using multiple monitoring results; and the HACCP plan did not list the procedures to verify effective implementation and/or frequency of these procedures.

NOTE: The deficiencies listed above were not identified by either establishment or inspection personnel. Corrective action was not initiated until the need was identified by the FSIS auditor.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
11/15/01	Est. 272-M/S Cesare Fiorucci S.P.A.	Santa Palomba COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr.Alessandra Di Sandro, Dr.Adriano Giorgioni	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

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FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	11/15/01	Est. 272-M/S Cesare Fiorucci S.P.A.	Santa Palomba COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr.Alessandra Di Sandro, Dr.Adriano Giorgioni	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

COMMENTS:

11. Light was inadequate at the hog head inspection station. Establishment officials ordered correction.

26. An employee was not observing good hygienic work habits to prevent product contamination such as: he was observed picking up pieces of meat from the floor and, without washing his hands, handled edible product in the boning room. Establishment officials took corrective action immediately.

28. Dirty water was falling from carcass splitting saw onto hog carcass during carcass splitting in the slaughter room. Neither establishment nor GOI meat inspection officials took corrective action.

41. Inspector was not incising and observing mandibular lymph nodes of hog heads. The mesenteric lymph nodes and spleen were not palpated as required in Council Directive 64/433/EEC of 26 June 1964. GOI inspection officials did not take any corrective actions.

43. Inedible product was not denatured/decharacterized or under security before shipping for rendering.

76. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation: the HACCP plan did not list the procedures to verify effective implementation and/or frequency of these procedures.

NOTE: The deficiencies listed above were not identified by either establishment or inspection personnel. Corrective action was not initiated until the need was identified by the FSIS auditor.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
11/23/01	Est. 304 M/S Mec Carni S.P.A.	Macaria (MN) COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Castoldi, Dr. Noe, and Dr. Pasin	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 O
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	02 O	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 O
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 A	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 A	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 U	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 A	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection	71 O
Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 A	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 A	Inspection supervision	76 U
Dry storage areas	21 A	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 C
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	82 M
Personal hygiene practices	26 A	Ingredients identification	53 O		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 O		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY / COUNTRY
	11/23/01	Est. 304 M/S Mec Carni S.P.A.	Macaria (MN) ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Castoldi, Dr. Noe, and Dr. Pasin	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

COMMENTS:

40. Hogs were not stunned in such a manner that they would be rendered unconscious with a minimum excitement and discomfort. A few hogs were observed staggering and crawling on the top of other stunned hogs and their throats were slit by the employee without further stunning. Establishment officials ordered correction.

43. Inedible product was not denatured/decharacterized or under security before shipping for rendering.

76. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

82. The establishment's HACCP program met the basic requirements, but the HACCP plans(s) did not address adequately the applicable regulatory requirements for implementation: there was no description of corrective action to be taken when a critical limit was exceeded; the HACCP plan had not been validated using multiple monitoring results; and the HACCP plan did not list the procedures to verify effective implementation and/or frequency of these procedures.

NOTE: The deficiencies listed above were not identified by either establishment or inspection personnel. Corrective action was not initiated until the need was identified by the FSIS auditor.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
11/21/01	Est. 312-M/S Coop. Agricola Bertana S.r.L.	Castelverde
		COUNTRY: ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Noe and Dr. Castoldi	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
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1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 O
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 O
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 A	Container closure exam	66 O
Lighting	11 M	Antemortem inspec. procedures	38 A	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 A	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection	71 O
Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
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Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	82 M
Personal hygiene practices	26 A	Ingredients identification	53 O		
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FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	11/21/01	Est. 312-M/S Coop. Agricola Bertana S.r.L.	Castelverde COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Noe and Dr. Castoldi	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

COMMENTS:

11. Light was inadequate and not shadow proof at the hog head, viscera, and carcass inspection stations in the slaughter room. Establishment officials ordered correction.

43. Inedible product was not denatured/decharacterized or under visual inspectional supervision or locked or sealed before shipping for rendering. It was kept in the open containers outside the premises. Establishment officials ordered correction.

76. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation: the flow diagram was not completed or did not include all process steps and product flow; the hazard analysis had not been conducted or was not complete; there was not a critical limit and/or monitoring frequency for each CCP; there was no description of corrective action to be taken when a critical limit was exceeded; and the HACCP plan did not list the procedures to verify effective implementation and/or frequency of these procedures.

NOTE: The deficiencies listed above were not identified by either establishment or inspection personnel. Corrective action was not initiated until the need was identified by the FSIS auditor.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
12-05-01	Est. 316-L Emilia Romagna-Tanara Giancarlo	Langhirano
		COUNTRY: Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Dr. Cesare Allodi	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unaccep

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Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	
Pest --no evidence	07 M	Operational sanitation	35 M	Processing records	
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Pest control monitoring	09 A	2. DISEASE CONTROL		Filling procedures	
Temperature control	10 A	Animal identification	37 O	Container closure exam	
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	
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Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	
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Over-product equipment	18 A	3. RESIDUE CONTROL		Export certificates	
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Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL		"Equal to" status	
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 O	Imports	
Personal dress and habits	25 A	Boneless meat reinspection	52 O		
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 O		

FOREIGN PLANT REVIEW FORM (reverse)	12-05-01	Est. 316-L Emilia Romagna-Tanara Giancarlo	Langhirano
			COUNTRY Italy
NAME OF REVIEWER Dr. Oto Urban	NAME OF FOREIGN OFFICIAL Dr. Cesare Allodi	EVALUATION [X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable	

COMMENTS:

7 Spider web was observer on the ceiling and wooden racks for ham in the drying room. This deficiency was corrected immediately by the establishment management.

19 Few deep cuts were observe in the conveyor belt in the salting room. This was scheduled for correction by the establishment.

30 Several hams were observed contacting the wall and the door in the resting and the drying room. This deficiency was corrected immediately by the establishment management.

34, 35 The government inspector was performing pre-operational sanitation twice or three times a year and operational sanitation at least once a week. The operational sanitation did not include cleaning procedures.

43 The inedible plastic container was not identified in the salting room. This was scheduled for correction by the establishment. The inedible product have not been denatured in this establishment.

76 The FSIS auditors could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
11/22/01	Est. 335-L CIM Alimbntari SPA	Emilia Romagna
		COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Cozzolino, Local Supervisor	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
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Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
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Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 U
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	82 M
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY / COUNTRY
	11/22/01	Est. 335-L CIM Alimbntari SPA	Emilia Romagna / ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Cozzolino, Local Supervisor	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

COMMENTS:

7. Gaps at the bottoms of door in the shipping room were not sealed properly to prevent the entry of rodents and other vermin. Establishment officials ordered correction immediately.

34, 35. GOI meat inspection officials were not adequately monitoring/verifying the adequacy and effectiveness of the pre-operational and operational sanitation SSOP. Inspector was performing pre-operational sanitation once a month and operational sanitation between three to four times a year.

43 A. Edible and inedible product containers were not identified to prevent possible cross-contamination and/or cross utilization in the boning room. Establishment officials ordered correction immediately.
B. Inedible product was not denatured/decharacterized or under security before shipping for rendering.

76 A. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.
B. GOI meat inspection officials were not providing daily adequate inspection covereage. Inspector was visiting the establishment two to three times a week (the establishment operates five days per week) and the duration of the visits was between one to two hours.

79. Species verification was not carried out as required by FSIS.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation: the flow diagram was not completed or did not include all process steps and product flow; there was not a critical limit and/or monitoring frequency for each CCP; the HACCP plan had not been validated using multiple monitoring results; and the HACCP plan did not list the procedures to verify effective implementation and/or frequency of these procedures.

NOTE: The deficiencies listed above were not identified by either establishment or inspection personnel. Corrective action was not initiated until the need was identified by the FSIS auditor.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
11/28/01	Est. 363-L Montorse Francesco e Figli S.P.A.	Villa Franca
		COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Foroni, Supervisor, & Dr. Residoni, IIC	☐ Acceptable ☐ Acceptable/ Re-review ☒ Unacceptable

CODES (Give an appropriate code for each review item listed below)
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FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY / COUNTRY
	11/28/01	Est. 363-L Montorse Francesco e Figli S.P.A.	Villa Franca ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Foroni, Supervisor, & Dr. Residoni, IIC	☐ Acceptable ☐ Acceptable/ Re-review ☒ Unacceptable

COMMENTS:

17. Dripping condensate, from overhead refrigeration units, ceilings, beams, and pipes that were not cleaned/sanitized daily, in fresh product receiving room, corridors, fresh product cooler, and boning room was falling onto exposed edible product. This is a repeat deficiency from the last audit. Neither establishment nor GOI meat inspection officials took corrective action.

19. Numerous racks for edible product ready for use in the fresh product receiving room were found with fat and pieces of meat from the previous day's operation. Neither establishment nor GOI meat inspection officials took corrective action.

21. Cobwebs and dirt were observed in the dry storage room and packaging material was not stored on racks high enough to monitor pest control and sanitation programs.

30. Hams were contacting unclean fork lift during transportation in the receiving room. Establishment officials took corrective action immediately.

34, 35 A. The daily pre-operational sanitation monitoring records did not reflect the actual sanitation conditions observed in the establishment and operational sanitation monitoring record was not adequately maintained.
B. The GOI meat inspection officials were not adequately monitoring/verifying the adequacy and effectiveness of the pre-operational and operation sanitation SSOP. The daily pre-operational sanitation monitoring was performed twice a month.

43. Inedible product was not denatured/decharacterized or under security before shipping for rendering.

76. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

79. Species verification testing was not carried out as required by FSIS.

80. Because of gross product contamination and lack of a compliance with daily pre-operational and operational sanitation/equivalent sanitation programs and procedures, inadequate inspectional controls, and noncompliance with basic regulatory requirements of HACCP program, the status of this establishment is not equivalent to that required in the U.S. program. All of the above deficiencies were discussed with Dr. Foroni, Supervisor, and Dr. Residoni, IIC, and they agreed to remove Establishment 363-L from the list of establishments eligible to export meat and meat products to the United States, effective November 28, 2001.

82. This establishment did <u>not</u> meet some of the FSIS basic regulatory requirements of the HACCP program. In addition, the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation: the hazard analysis had not been conducted or was not complete; there was not a HACCP plan for each product where a hazard had been identified; there was not a critical limit and/or monitoring frequency for each CCP; the HACCP plan had not been validated using multiple monitoring results; the HACCP plan did not list the procedures to verify effective implementaiton and/or frequency of these procedures; pre-shipment document reviews were not being conducted by establishment officials.

NOTE: This establishment was evaluated as acceptable/re-review in last audit in May 2001.

NOTE: The deficiencies listed above were not identified by either establishment or inspection personnel. Corrective action was not initiated until the need was identified by the FSIS auditor.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
11/30/01	Est. 368-L Wuber SPA	Medolago
		COUNTRY: ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Castoldi & Dr. Raccagni Mario, IIC	[X] Acceptable [ ] Acceptable/Re-review [ ] Unacceptable

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Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 O	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76 U
Dry storage areas	21 M	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	82 M
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	11/30/01	Est. 368-L Wuber SPA	Medolago
			COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Castoldi & Dr. Raccagni Mario, IIC	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

COMMENTS:

7, 21. Gaps at the sides of door in the dry storage room were not sealed properly to prevent the entry of rodents and other vermin. Establishment officials ordered correction immediately.

31. Product that contacted the floor was not reconditioned in a sanitary manner before being added to the edible product and facility for reconditioning drop meat was inadequate such as designated area with adequate light. Establishment officials ordered correction immediately.

34, 35 A. The daily operational sanitation deficiencies were not identified and any corrective actions taken were not documented by the establishment personnel. Establishment officials ordered correction.
B. GOI meat inspection officials were not adequately monitoring/verifying the adequacy and effectiveness of the pre-operational and operational sanitation SSOP. The daily pre-operational sanitation monitoring deficiencies were not identified and any corrective actions taken were not documented. The daily pre-operational sanitation monitoring was performed once a week.

43. Inedible product was not denatured/decharacterized or under security before shipping for rendering.

76. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation: there was not a critical limit and/or monitoring frequency for each CCP; there was no description of corrective action to be taken when a critical limit was exceeded; and the HACCP plan did not list the procedures to verify effective implementation and/or frequency of these procedures.

NOTE: The deficiencies listed above were not identified by either establishment or inspection personnel. Corrective action was not initiated until the need was identified by the FSIS auditor.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
12/05/01	Est. 442-L Levoni SPA	San Daniele D Friul
		COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Caliz & Dr. Alessandro Visentini	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	02 O	Product reconditioning	31 M	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 M	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 O	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76 U
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 (
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	82 M
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	12/05/01	Est. 442-L Levoni SPA	San Daniele D Friul COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Caliz & Dr. Alessandro Visentini	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

COMMENTS:

31. Product that contacted the floor was not reconditioned in a sanitary manner before being added to the edible product and facility for reconditioning drop meat was inadequate such as designated area with adequate light. Establishment officials ordered correction immediately.

34, 35. GOI meat inspection officials were not adequately monitoring/verifying the adequacy and effectiveness of the pre-operational and operational sanitation SSOP. The daily pre-operational sanitation monitoring was performed one to two times a month.

43 A. Edible and inedible product containers were not identified in the fresh ham receiving room. Establishment officials took corrective action immediately.
B. Inedible product was not denatured/decharacterized or under security before shipping for rendering.

76 A. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.
B. The supervisory visits that were performed were not done monthly. Only four visits were conducted per year by the local district/provincial officials.
C. GOI meat inspection officials were not providing adequate daily inspection coverage. Inspector was visiting establishment one to two times a week (the establishment operates five days per week) and between one to two hours each visit.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation: the hazard analysis had not been conducted or was not complete; there was no description of corrective action to be taken when a critical limit was exceeded; the HACCP plan had not been validated using multiple monitoring results; the HACCP plan did not list the procedures to verify effective implementation and/or frequency of these procedures; and there were no records produced for monitoring of the HACCP plan CCPs, or the records did not show actual values and observations.

FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

12-04-01	Est. 476-L Salumificio GIULLE s.p.a.	Langhirano
		COUNTRY Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Drs. Cesare Allodi & Alberto Paratica	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 M	Laboratory confirmation	57 A
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 N	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 O
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 O
Pest --no evidence	07 A	Operational sanitation	35 M	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 O
Equipment approval	16 O	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 M	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76 U
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 O	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	82 M
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 O		

FOREIGN PLANT REVIEW FORM (reverse)	12-04-01	Est. 476-L Salumificio GIULLE s.p.a.	COUNTRY Italy
NAME OF REVIEWER Dr. Oto Urban	NAME OF FOREIGN OFFICIAL Drs. Cesare Allodi & Alberto Paratica	EVALUATION [X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable	

COMMENTS:

17 The flaking paint over the table used for introducing the fat on hams was observed in the fatting room. This was scheduled for correction by the establishment.

30 Several hams were observe contacting walls in the salting and drying rooms. This was corrected immediately by the establishment official.

34, 35 The government inspector was performing pre-operational sanitation once a month and operational sanitation once a week. The table used for salting is checked during the preoperational sanitation but was not included in the procedure and the preventive action was missing.

43 The inedible product was not being denatured in this establishment.

76. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	COUNTRY
11-23-01	Est. 480-L Prosciuttificio "Il Mulino SPA"	Parma Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Dr. Allodi Cesare	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL							
(a) BASIC ESTABLISHMENT FACILITIES		Cross contamination prevention	28 A	Formulations	55 A
		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 A
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 N	Special label claims	59 O
Hand washing facilities	04 M	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring	60 O
Sanitizers	05 A	Effective maintenance program	33 M	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 O
Pest --no evidence	07 M	Operational sanitation	35 M	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 M	2. DISEASE CONTROL		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 O
Equipment approval	16 O	Condemned product control	43 U	6. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	3. RESIDUE CONTROL		Export certificates	74 A
Product contact equipment	19 M	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76 U
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 O
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	82
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE 11-23-01	Est. 480-L Prosciuttificio "Il Mulino SPA"	Parma / COUNTRY Italy
NAME OF REVIEWER Dr. Oto Urban	NAME OF FOREIGN OFFICIAL Dr. Allodi Cesare	EVALUATION [X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable	

COMMENTS:

4 Hand-operated waste receptacles observed in two dressing rooms and no paper towel at the hand washing facility observed in one dressing room. These deficiencies were corrected immediately by the establishment management.

7 Insect and and spider web observed in the drying room. This was corrected immediately by the company employee.

9 There is no corrective action taken by the contracting company in case of repeated findings of rodent activity in the same location. The frequency of visits is also insufficient (4 times a year). This deficiency was scheduled for correction.

19 The conveyor belt had several deep cuts in the salting room. This was scheduled for correction by the establishment officials.

7/33 There was a space large enough for rodent to get under the door in the shipping area. This deficiency was scheduled for correction by the establishment officials.

34, 35 The daily pre-operational sanitation deficiencies were not clearly identified and the government inspector was performing pre-operational and operational sanitation twice a week.

43 The inedible product was not denatured in this establishment.

76. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation. Hazard analysis decisions were not justified, corrective actions to be taken when critical limits were exceeded were not sufficiently described, and the description of the verification of the CCP was not specific, but rather a combination of several CCPs.

FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

11-19-01	Est. 492-L Lombardia Salumficio Menatti SRL	Plantedo COUNTRY Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Dr. Luigi Festa	☐ Acceptable ☒ Acceptable/ Re-review ☐ Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 M	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 M	Laboratory confirmation	57 A
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 O
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 U	Processing equipment	62 O
Pest --no evidence	07 A	Operational sanitation	35 M	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 O
Equipment approval	16 O	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 M	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 M	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76 U
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 C
Personal dress and habits	25 A	Boneless meat reinspection	52 A		
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	Piantedo
	11-19-01	Est. 492-L Lombardia Salumficio Menatti SRL	COUNTRY Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Dr. Luigi Festa	☐ Acceptable . ☒ Acceptable/ Re-review ☐ Unacceptable

COMMENTS:

17 Flaking paint over the product observed in the cooler and over the product area in the massaging room. This was scheduled for correction by the establishment.

19 Dry meat was observed on the brine pumping equipment after the pre-operational sanitation.

28 Several clean metal cars and edible plastic bins were contacting the floor with the edge used for processing edible product in the area of pumping room, spice room storage and halls. This was corrected immediately by the establishment officials.

3o Hair and oil found on hams in the receiving cooler. This deficiency was corrected immediately by the establishment officials.

34,35 The government inspector was present in the plant for 1.5 hrs a day, five days a week. The pre-operational sanitation was performed 2 or 3 times a month. The establishment SSOP records did not indicate any deficiencies during the cleaning while some deficiencies were found during the on-site visit. Additionally, there was too much time given by the inspection service for correction of the deficiency that required immediate attention. This was scheduled for correction by the establishment and the Inspection Service.

43 Inedible and edible plastic barrels were not properly identified in the casing room. This deficiency was scheduled for correction by the establishment.

43 The inedible product is not denatured in this establishment.

76 (a) The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

76 (b) The internal review records indicated that the reviewer had requested a boning table in May 2001; this request had not yet been fulfilled. Immediate correction was performed by the establishment officials.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
12/06/01	Est. 500-L Carpegna Prosciutti SPA	Carpegna
		COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Magalotti, Veterinarian in Charge	☐ Acceptable ☐ Acceptable/ Re-review ☒ Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 M	Laboratory confirmation	57 O
Chlorination procedures	02 O	Product reconditioning	31 M	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 M	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
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Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 O	Export product identification	72 A
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Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
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Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 (
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 U
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 /
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	82 U
Personal hygiene practices	26 U	Ingredients identification	53 A		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	12/06/01	Est. 500-L Carpegna Prosciutti SPA	Carpegna COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Magalotti, Veterinarian in Charge	☐ Acceptable ☐ Acceptable/ Re-review ☒ Unacceptable

COMMENTS:

19. Fat residue and dirt from previous days' operation was observed on working table ready for use in processing room. Establishment officials ordered correction. This is a repeat deficiency from last audit.

26. An employee was not observing good hygienic work habits to prevent product contamination in the deboning room such as: employee handling unclean inedible product container and, without washing hands, handled edible product. Neither establishment nor GOI inspection officials took corrective action.

30. Hams were contacting inedible product containers and walls in the deboning room. Establishment officials ordered correction.

31. Product that contacted the floor was not reconditioned in a sanitary manner before being added to the edible product and facility for reconditioning drop meat was inadequate such as designated area with adequate light. Establishment officials ordered correction immediately. This is a repeat deficiency from the last audit.

34, 35 A. The daily pre-opeational and operational sanitation monitoring deficiencies were not identified and any corrective actions taken were not documented by the establishment personnel and SSOP records did not reflect the actual sanitary conditions observed in the establishment.

B. GOI meat inspection officials were not adequately monitoring/verifying the adequacy and effectiveness of the pre-operational and operational sanitation SSOP. The daily pre-operational sanitation monitoring was performed once and operational sanitation three times a week but no record was maintained.

43 A. A few edible and inedible product containers were not identified to prevent possible cross-contamination and/or cross utilization in ham deboning room. This is a repeat deficiency from the last audit.

B. Inedible product was not denatured/decharacterized or under security before shipping for rendering. This is a repeat deficiency from the last audit.

76 A. Jan 1 - Dec. 6 - there were monthly supervisory visits but not a single deficiency was identified. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

B. GOI meat inspection officials were not providing daily adequate inspection coverage. Inspector was visiting establishment three times a week (the establishment was operating five days a week) and the duration of visits was between five to six hours.

80. Because of product contamination, lack of compliance with daily pre-operational and operational sanitation/equivalent sanitation programs and procedures, inadequate inspectional controls, and noncompliance with FSIS basic regulatory requirements of HACCP program, the status of this establishment is not equivalent to that required in the U.S. program. All the above deficiencies were discussed with Dr. Magalotti, IIC, and he agreed to remove Establishment 500-L from the list of establishments eligible to export meat and meat products to the United States, effective December 6, 2001.

82. This establishment did <u>not</u> meet some of the FSIS basic regulatory requirements of the HACCP programs. In addition, the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation: the flow diagram was not completed or did not include all process steps and product flow; the hazard analysis had not been conducted or was not complete; the intended use of the product or end user had not been identified; there was not a critical limit and/or monitoring frequency for each CCP; there was no description of corrective action to be taken when a critical limit was exceeded; the HACCP plan had not been validated using multiple monitoring results; the HACCP plan did not list the procedures to verify effective implementation and/or frequency of these procedures; and there were no records produced for monitoirng of the HACCP plan CCPS, or the records did not show actual values and observations.

NOTE: This establishment was recommended for re-review during the last audit in May 2001.

NOTE: The deficiencies listed above were not identified by either establishment or inspection personnel. Corrective action was not initiated until the need was identified by the FSIS auditor.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	
11-30-01	Est. 513-L Italfine S.R.L.	Cormiglio
		COUNTRY: Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Dr. Cesare Allodi	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 A
Chlorination procedures	02 O	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 N	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 O
Sanitizers	05 M	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 O
Pest --no evidence	07 A	Operational sanitation	35 M	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 O
Equipment approval	16 O	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 M	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 M	Sampling procedures	47 O	Inspection supervision	76
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	7
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	7
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	8
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	8
Personal dress and habits	25 A	Boneless meat reinspection	52 A	HACCP	8
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 O		

FOREIGN PLANT REVIEW FORM (reverse)	11-30-01	Est. 513-L Italfine S.R.L.	COUNTRY Italy
NAME OF REVIEWER Dr. Oto Urban	NAME OF FOREIGN OFFICIAL Dr. Cesare Allodi	EVALUATION [X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable	

COMMENTS:

5 The water temperature was 78-79C in sanitizer in the trimming room. This deficiency was corrected immediately by the establishment officials.

17 The flaking paint was observed over the table used for edible product in the fatting room. This was scheduled for correction by the establishment management.

20 The plastic container with equipment parts used for processing edible product was observed to be set directly on the floor. This deficiency was corrected immediately by the establishment management.

34, 35 Dirty equipment (meat scraps on table and conveyor belt) were observed in the deboning room. This deficiency was corrected immediately by the establishment employees. The SSOP procedure's preventive action was missing. This was scheduled for correction by the establishment management. The government inspector was performing pre-operational sanitation twice a month and operational sanitation three times in two weeks.

43 The inedible product was not denatured in this establishment

76. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation.

FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

11-27-01	Est. 514-L Unibon Salumi	Langhirano
		COUNTRY Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Dr. Zacharini	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
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Water potability records	01 A	Product handling and storage	30 M	Laboratory confirmation	57 A
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 N	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 O
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 O
Pest --no evidence	07 A	Operational sanitation	35 M	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 M	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 O
Equipment approval	16 O	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76 U
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 O	Imports	81 O
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	82 N
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 O		

FOREIGN PLANT REVIEW FORM (reverse)	11-27-01	Est. 514-L Unibon Salumi	Langhirano
			COUNTRY Italy
NAME OF REVIEWER Dr. Oto Urban	NAME OF FOREIGN OFFICIAL Dr. Zacharini	EVALUATION [X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptab	

COMMENTS:

11 Inspection table needs to be installed under the sufficient light in the ham receiving area. This deficiency will be corrected by the establishment.

30 Excessive hair found on several carcasses in the different stage of drying and salting. The corrective action will be taken by the establishment management.

34, 35 Preventive action was missing and corrective action was worked out for the operational sanitation but not for the preoperationa sanitation. The government inspector was performing pre-operational sanitation twice a year and operational sanitation once a week and when asked by the establishment.

43 The inedible product was not denatured in this establishment.

76. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE: 12/14/01

ESTABLISHMENT NO. AND NAME: Est. 550-L Casale SPA

CITY: Felino

COUNTRY: ITALY

NAME OF REVIEWER: Dr. Faizur R. Choudry

NAME OF FOREIGN OFFICIAL: Dr. Borteli, IIC; Dr. Daate; Dr. Noe, Dr. Lidi

EVALUATION: [X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
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(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
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Chlorination procedures	02 O	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 O	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
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Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 (
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 /
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	82 M
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	12/14/01	Est. 550-L Casale SPA	Felino COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Borteli, HC; Dr. Daate; Dr. Noe, Dr. Lidi	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

COMMENTS:

43. Inedible product was not denatured/decharacterized or under security before shipping for rendering.

76 A. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.
B. GOI meat inspection officials were not providing daily adequate inspection coverage. Inspector was visiting establishment three times a week (the establishment was operating five days a week) and the duration of visits was one hour.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation: the hazard analysis had not been conducted or was not complete; there was not a HACCP plan for each product where a hazard had been identified; and the HACCP plan had not been validated using multiple monitoring results.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
12/11/01	Est. 586-L F. Lli Galloni SPA	Langhirano
		COUNTRY: ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Pierantoni & Dr. Allodi	[X] Acceptable [ ] Acceptable/Re-review [ ] Unacceptable

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Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 M	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
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Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 O	Export product identification	72 A
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Welfare facilities	23 O	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	82 M
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	12/11/01	Est. 586-L F. Lli Galloni SPA	Langhirano COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Pierantoni & Dr. Allodi	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

COMMENTS:

31. Product that contacted the floor (drop meat) was not reconditioned in a sanitary manner before being added to the edible product and facility for reconditioning drop meat was inadequate such as designated area with adequate light. Establishment officials ordered correction immediately.

34, 35. GOI meat inspection officials were not adequately monitoring/verifying the adequacy and effectiveness of the pre-operational and operational sanitation SSOP. Inspector was performing pre-operational sanitation once a month.

43. Inedible product was not denatured/decharacterized or under security before shipping for rendering.

76 A. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.
B. GOI meat inspection officials were not providing daily adequate inspection coverage. Inspector was visiting the establishment two times a week (the establishment operates five days per week) and the duration of visits was two hours.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation: the flow diagram was not completed or did not include all process steps and product flow; the hazard analysis had not been conducted or was not complete; and the HACCP plan did not list the procedures to verify effective implementation and/or frequency of these procedures.

NOTE: The deficiencies listed above were not identified by either establishment or inspection personnel. Corrective action was not initiated until the need was identified by the FSIS auditor.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
11-20-01	Est. I-632-L Rigamonti Sacunificio SPA	Mazzo Di Vina
		COUNTRY: Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Dr. Filippo Castoldi	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

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Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
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Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 O
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Personal dress and habits	25 M	Boneless meat reinspection	52 O		
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	11-20-01	Est. I-632-L Rigamonti Sacunificio SPA	Mazzo Di Vina COUNTRY Italy
NAME OF REVIEWER Dr. Oto Urban	NAME OF FOREIGN OFFICIAL Dr. Filippo Castoldi	EVALUATION [X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable	

COMMENTS:

8 Insectocutors were observed over the product in the final product processing and storage areas. Establishment will install them in different areas of the establishment

25 The street cloth of the company employee was not completely covered by his working cloth. This deficiency was corrected by the establishment personnel.

34,35 Inspector was performing pre-operational and operational sanitation once a week.

43 The inedible product was not denatured in this establishment.

76 The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
12/10/01	Est. 643 M/S F. LLi Martelli S.P.A	Dosolo (MN)
		COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Noe; Dr. Castoldi & Dr. Festa A. Cell	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
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Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 A	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 A	Inspection supervision	76 U
Dry storage areas	21 A	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 O
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	82 M
Personal hygiene practices	26 A	Ingredients identification	53 O		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 O		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	12/10/01	Est. 643 M/S F. LLi Martelli S.P.A	Dosolo (MN) COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Noe; Dr. Castoldi & Dr. Festa A. Cell	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

COMMENTS:

11. Light at the hog viscera inspection station was inadequate and was not shadow proof. Establishment officials ordered correction immediately.

30. Dirty legs of rack for edible product was contacting edible product that stacked on top of each other. Establishment officials ordered correction immediately.

43. Inedible product was not denatured/decharacterized or under security before shipping for rendering.

76. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation: there was not a critical limit and/or monitoring frequency for each CCP; there was no description of corrective action to be taken when a critical limit was exceeded; the HACCP plan had not been validated using multiple monitoring results; and the HACCP plan did not list the procedures to verify effective implementation and/or frequency of these procedures.

NOTE: The deficiencies listed above were not identified by either establishment or inspection personnel. Corrective action was not initiated until the need was identified by the FSIS auditor.

FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE		COUNTRY
12-10-01	Est. 649-L Prosciuttificio Morgante S.P.A. San Daniele	ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Dr. Visentini	☐ Acceptable ☒ Acceptable/ Re-review ☐ Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 M	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 A
Chlorination procedures	02 O	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 O	Product transportation	32 N	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 O
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 O
Pest --no evidence	07 A	Operational sanitation	35 M	Processing records	63 O
Pest control program	08 M	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 O
Equipment approval	16 O	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 M	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76 U
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 O
Personal dress and habits	25 A	Boneless meat reinspection	52 A	HACCP	82 M
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 O		

FOREIGN PLANT REVIEW FORM (reverse)	12-10-01	Est. 649-L Prosciuttificio Morgante S.P.A.	COUNTRY ITALY
NAME OF REVIEWER Dr. Oto Urban	NAME OF FOREIGN OFFICIAL Dr. Visentini	EVALUATION ☐ Acceptable ☒ Acceptable/ Re-review ☐ Unacceptable	

COMMENTS:

8 Insectocuters located over the exposed product were observed in several rooms through the establishment. This deficiency was scheduled for correction by the establishment.

19 Several deep cuts were observed in the conveyor belt at the receiving area. This was scheduled for correction by the establishment.

19/34 Several ham hangers were observed dirty with pieces of meat and fat on them right after the washing in the salting room. This was directed for correction by the establishment veterinarian.

28 The employee trimming the edible product was constantly leaning at and contacting inedible container and than continue to work with edible product on the conveyor belt in the salting room. This employee was instructed to not to contact the inedible container but he still not washed his hands.

34, 35 The SSOP pre-operative corrective action was described in general terms. The establishment agreed to be more specific in describing the SSOP deficiencies. The government inspector was performing pre-operational sanitation once in seven to ten days and operational sanitation once or twice a week.

43 Inedible container was not identified as such and the table to work with edible product (trimming hams which contacted the floor) was identified as inedible and was instructed to be sanitized after the trimming of hams in the boning room. This procedure was incorrect and it will be changed by the establishment.

43 Metal inedible container was not identified as such in the salting room and inedible product was not denatured when leaving the establishment. The first deficiency was scheduled for the correction by the establishment and the second will be discussed with the Italian inspection officials in Rome.

76a The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

76b Internal reviews were performed only four times per year.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation. The plan did not describe what would happen to product in the event that critical limits were exceeded. The management officials agreed to correct this.

FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

	12-11-01	Est. 683-L Friuli Venezia Giulia Cesare Fiorucci SPA	San Daniele COUNTRY Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Dr. Ivonne Caliz	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptabl

CODES (Give an appropriate code for each review item listed below)
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1 CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 M	Laboratory confirmation	57 A
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 N	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 O
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 O
Pest --no evidence	07 A	Operational sanitation	35 M	Processing records	63 C
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 C
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 C
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 C
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 C
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 C
Inspector work space	13 A	Humane Slaughter	40 O	Incubation procedures	69 C
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 C
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 C
Equipment approval	16 O	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72
Over-product ceilings	17 A	Returned and rework product	45 A	Inspector verification	73
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74
Product contact equipment	19 A	Residue program compliance	46 O	Single standard	75
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81
Personal dress and habits	25 M	Boneless meat reinspection	52 A	HACCP	82
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 O		

FOREIGN PLANT REVIEW FORM (reverse)	12-11-01	Est. 683-L Friuli Venezia Giulia Cesare Fiorucci SPA	San Daniele COUNTRY Italy
NAME OF REVIEWER Dr. Oto Urban	NAME OF FOREIGN OFFICIAL Dr. Ivonne Caliz	EVALUATION [X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable	

COMMENTS:

25 The establishment employye street cloth was not completely covered with his working cloth in the salting room. This deficiency was corrected immediately by the establishment management.

30 Several hams were observed to contact the wall and protecting metal covering for the air circulation in the drying room. This was corrected immediately by the establishment management.

30 Several strings for hanging hams on the conveyor belt were observed to contact the inedible container in the salting room. This deficiency was corrected immediately by the establishment employee.

34, 35 The government inspector was performing pre-operational sanitation once in ten days and operational sanitation once a week. The SSOP records did not include the preventive action. This was scheduled for correction by the establishment.

43 The inedible product was not denatered in this establishment.

76a The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

76b Internal reviews were performed only three to four times per year.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	
11-26-01	Est. 688-L Fontane del Duca S.R.L.	Sala Baganza
		COUNTRY: Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Dr. Cesare Allodi	[X] Acceptable [ ] Acceptable/Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
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1 CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 A
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 N	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 O
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 O
Pest --no evidence	07 M	Operational sanitation	35 M	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 O
Equipment approval	16 O	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 M	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76 U
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 C
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 O	Imports	81 C
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	82 N
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 O		

FOREIGN PLANT REVIEW FORM (reverse)	11-26-01	Est. 688-L Fontane del Duca S.R.L.	COUNTRY Italy
NAME OF REVIEWER Dr. Oto Urban	NAME OF FOREIGN OFFICIAL Dr. Cesare Allodi	EVALUATION [X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable	

COMMENTS:

7 Insectocutor observed over the product in several areas on the establishment. This was scheduled for correction by the establishment.

19 Several plastic trays were observed to be broken and metal racks were observed with pieces of fat. This deficiency was corrected immediately by the establishment.

34, 35 The SSOP pre-operational sanitation preventive action was missing and deficiencies were not clearly identified. The government inspector was performing pre-operational sanitation once in two months and operational sanitation once a week for one hour.

43 The inedible product was not denatured in this establishment.

76. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation.

INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

12/14/01

Est. 714-L Levoni S.P.A.

COUNTRY: Italy

NAME OF REVIEWER: Dr. Oto Urban

NAME OF FOREIGN OFFICIAL: Dr. Cesare Allodi

EVALUATION: [X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
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1. CONTAMINATION CONTROL		Cross contamination prevention	28 M	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
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Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
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Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
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(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
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Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
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Personal dress and habits	25 A	Boneless meat reinspection	52 A	HACCP	82 M
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 O		

FOREIGN PLANT REVIEW FORM (reverse)	12/14/01	Est. 714-L Levoni S.P.A.	COUNTRY Italy
NAME OF REVIEWER Dr. Oto Urban	NAME OF FOREIGN OFFICIAL Dr. Cesare Allodi	EVALUATION [X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable	

COMMENTS:

19 Dirty racks were observed in the fatting room. This deficiency was corrected immediately by the establishment employee.

28 Small pieces of stones were found on the product in the salting room. This was corrected by the establishment.

34, 35 The government inspector was performing pre-operational sanitation once a month and operational sanitation once a week.

43 The inedible product was not denatured by this establishment.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
12/04/01	Est. 720-L A E B Prosciutti SPA	San Daniele D Friuli
		COUNTRY: ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Caliz	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
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1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
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Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY / COUNTRY
	12/04/01	Est. 720-L A E B Prosciutti SPA	San Daniele D Friuli ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Caliz	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

COMMENTS:

31. Product that contacted the floor (drop meat) was not reconditioned in a sanitary manner before being added to the edible product and facility for reconditioning drop meat was inadequate such as designated area with adequate light. Establishment officials ordered correction immediately.

34, 35. GOI meat inspection officials were not adequately monitoring/verifying the adequacy and effectiveness of the pre-operational and operational sanitation SSOP. The daily pre-operational sanitation monitoring was performed one to two times a month.

43. Inedible product was not denatured/decharacterized or under security before shipping for rendering.

76 A. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.
B. The supervisory visits that were performed were not done monthly. Only four visits were conducted per year by the local district/provincial officials.
C. GOI meat inspection officials were not providing adequate daily inspection coverage. Inspector was visiting establishment one to two times a week (the establishment operates five days per week) and the duration of visits was between one to two hours.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation: the hazard analysis had not been conducted or was not complete; the HACCP plan had not been validated using multiple monitoring results; and the HACCP plan did not list the procedures to verify effective implementation and/or frequency of these procedures.

NOTE: The deficiencies listed above were not identified by either establishment or inspection personnel. Corrective action was not initiated until the need was identified by the FSIS auditor.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	
11-22-01	Est. 744-L Parmacotto S.P.A.	Sala Baganza
		COUNTRY: Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Dr. Noe & Pierantoni	☐ Acceptable ☒ Acceptable/ Re-review ☐ Unacceptable

CODES (Give an appropriate code for each review item listed below)
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Establishments separation	06 A	Preoperational sanitation	34 U	Processing equipment	62 O
Pest --no evidence	07 M	Operational sanitation	35 M	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 M	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 O
Equipment approval	16 O	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76 U
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 C
Personal dress and habits	25 A	Boneless meat reinspection	52 A	HACCP	82 M
Personal hygiene practices	26 A	Ingredients identification	53 A		83
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	11-22-01	Est. 744-L Parmacotto S.P.A.	Data Bagatza COUNTRY Italy
NAME OF REVIEWER Dr. Oto Urban	NAME OF FOREIGN OFFICIAL Dr. Noe & Pierantoni	EVALUATION ☐ Acceptable ☒ Acceptable/ Re-review ☐ Unacceptable	

COMMENTS:

5 The sanitizer in the receiving room did not have enough water. This was corrected immediately by the establishment officials.

7 Spider webs were observed in the receiving cooler. This deficiency was corrected immediately by the establishment officials.

7/9 There was a space under the door sufficient for rodent to get in to the shipping room. The frequency of rodent control performed by the contracted company was not sufficient (every second month). This was scheduled for correction by the establishment officials.

28 The plastic felt down on the floor was picked up by an employee who did not change his gloves and continue to work in the molding room. The company scheduled the training of the employee.

30 Oil spots were found on the ham in two cases in the receiving cooler. This was corrected immediately by the establishment employee.

34, 35 Several dirty equipment (metal bins) with pieces of meat and fat observed in the massaging room. This deficiency was found despite of a report of the proper task accomplishment from the pre-operational sanitation monitoring and verification personnel. This deficiency requires employee training, which will be performed by the company. The government inspector was performing pre-operational and operational sanitation twice or three times a week for two hours.

43 There was no identification of inedible metal cars in the storage room next to the pumping of hams. This was scheduled for correction by the company employees. The condemned product is not denatured in Italy.

58 There is an incorrect statement on the label of Leonardo ham declaring that the pigs used are from Italy. The origin of pigs is from Denmark. The establishment scheduled this deficiency for correction.

76. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation. Corrective actions to be taken when critical limits were exceeded were not sufficiently described and clarification was needed regarding the intended consumers of the finished product.

FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

11-29-01	Est. 758-L Langhiranese Prosciutti S.R.L.	Langhirano COUNTRY Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Drs. Allodi & Stefano	☐ Acceptable ☒ Acceptable/ Re-review ☐ Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 M	Laboratory confirmation	57 A
Chlorination procedures	02 O	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 N	Special label claims	59 O
Hand washing facilities	04 M	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 O
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 O
Pest --no evidence	07 A	Operational sanitation	35 M	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 M	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 M	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 O
Equipment approval	16 O	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 M	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 M	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76 U
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 O
Personal dress and habits	25 A	Boneless meat reinspection	52 A	HACCP	82 M
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 O		

FOREIGN PLANT REVIEW FORM (reverse)	11-29-01	Est. 758-L Langhiranese Prosciutti S.R.L.	COUNTRY Italy
NAME OF REVIEWER Dr. Oto Urban	NAME OF FOREIGN OFFICIAL Drs. Allodi & Stefano	EVALUATION ☐ Acceptable ☒ Acceptable/ Re-review ☐ Unaccep	

COMMENTS:

4 Paper towel was found to continuously contacting piece of equipment. This deficiency was corrected immediately.

9 Insectocuters were observed over the product in several areas in the establishment. This was scheduled for correction by the establishment.

11 Inspection table and sufficient light were missing in the meat receiving room. This was scheduled for correction.

17 Flaking paint close to the product but not over it was observed in the salting room and drying room. This was scheduled for correction by the establishment management.

19/34 Plastic plates used for ham salting were not clean before the start of operation in the salting room. There was no immediate corrective action by the establishment or inspection service.

19/34 The conveyor belt was found with pieces of dry meat before operation in the receiving room. No corrective action performe either by the company or inspection service.

19/35 Clean and dirty plastic plates were not separated after the washing. No corrective action by the establishment or the inspectio service were observed.

30 Product (remains of hams) were observed on the wall in the drying room. No corrective action by the establishment was perfor during the audit.

34/35 The preoperational and operational sanitation deficiencies observed were not reported in the SSOP documents. This is going be corrected by the establishment. The SSOP preventive action was not performed and deficiencies observed during the audit were recorded in the SSOP records. The government inspector was performing pre-operational sanitation once a month and operational sanitation once a week.

43 Inedible barrels were used for storing edible product in the salting room. The corrective action observed was removal of inedit mark from the barrel by the consortium representative. The new edible container contained inedible product and equipment that ha not been washed The inedible product was not denatured in this establishment.

76. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to highe levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation. A portion of the corrective action was misplaced under monitoring activit and CCPs were not defined by number.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
11/26/01	Est. 791 M/S Italcarni Soc. Coop. A.R.L.	Migliarina Di Carpi
		COUNTRY: ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Pierantoni, Dr. Noe, & Dr. Emore Vezzani	[X] Acceptable [ ] Acceptable/Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 O
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	02 O	Product reconditioning	31 M	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 O
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 O
Pest --no evidence	07 M	Operational sanitation	35 A	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 A	Container closure exam	66 O
Lighting	11 M	Antemortem inspec. procedures	38 A	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 A	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection	71 O
Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 A	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 A	Inspection supervision	76 U
Dry storage areas	21 A	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 C
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 C
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	82 M
Personal hygiene practices	26 A	Ingredients identification	53 O		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 O		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	11/26/01	Est. 791 M/S Italcarni Soc. Coop. A.R.L.	Migliarina Di Carpi COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faizur R. Choudry	Dr. Pierantoni, Dr. Noe, & Dr. Enore Vezzani	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

COMMENTS:

07. Gaps at the bottoms of door in the deboning room and casing room were not sealed properly to prevent the entry of rodents and other vermin. Establishment officials ordered correction.

11. Light at the hog head inspection station was inadequate and was not shadow proof. Establishment officials ordered correction.

31. Product that contacted the floor (drop meat) was not reconditioned in a sanitary manner before being added to the edible product and facility for reconditioning drop meat was inadequate such as designated area with light, hand-washing, and sanitizing facility. Establishment officials ordered correction immediately.

43. Inedible product was not denatured/decharacterized or under security before shipping for rendering.

76. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective action in the even that the official veterinarian's performance did not meet requirements.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation: the HACCP plan had not been validated using multiple monitoring results; and the HACCP plan did not list the procedures to verify effective implementation and/or frequency of these procedures.

NOTE: The deficiencies listed above were not identified by either establishment or inspection personnel. Corrective action was not initiated until the need was identified by the FSIS auditor.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
11/16/01	Est. 989-L Corte Buona S.P.A.	Paliano (PR) COUNTRY: ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faiz Choudry & Dr. Oto Urban	Dr. Maestripieri, IIC & Dr. Pietro Noe	☐ Acceptable ☐ Acceptable/ Re-review ☒ Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable **M** = Marginally Acceptable **U** = Unacceptable **N** = Not Reviewed **O** = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 M	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
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Chlorination procedures	02 O	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 U	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 U	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 U	Processing records	63 A
Pest control program	08 M	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 O	Export product identification	72 A
Over-product ceilings	17 U	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 M	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 U	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76 U
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 I
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 U
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 /
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	82 U
Personal hygiene practices	26 M	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY / COUNTRY
	11/16/01	Est. 989-L Corte Buona S.P.A.	CITY: Paliano (PR) COUNTRY: ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faiz Choudry & Dr. Oto Urban	Dr. Maestripieri, IIC & Dr. Pietro Noe	☐ Acceptable ☐ Acceptable/ Re-review ☒ Unacceptable

COMMENTS:

05. Sanitizer was not working during the operation in the processing room. Neither establishment nor GOI meat inspection officials took corrective action. This is a repeat deficiency from the last audit.

07. Door was not effectively shut in the product receiving room and cover over the vent was broken in the smoking room. Flies were observed in the processing and packaging rooms. Establishment officials ordered correction.

17 A. Dripping condensate, from overhead refrigeration units that were not cleaned/sanitized dialy, was falling in one cooler. There was no product underneath at the time of audit. B. Dripping condensate, from ceilings that were not cleaned/sanitized daily, was falling onto hams in the cooking and smoking rooms and also ceilings were observed with mildew. Neither establishment nor GOI meat inspection officials took corrective action. This is a repeat deficiency from the last audit.

18. Overhead ceilings in the processing room were observed with accumulation of pieces of fat, meat, and dirt.

19, 28. In the processing rooms: containers for edible product were found with grease, fat, and broken; conveyor belt for edible product, brine injection equipment, working tables, and molds for ham were found with fat and pieces of meat from previous days' operation. This was a repeat deficiency from the last audit.

26. Several employees were not observing good hygienic work habits to prevent product contamination such as: plastic packaging material was contacting floor during packaging; cartons were kept on the floor and dirty steel was kept on the working table.

34. 35 A. The daily pre-operational and operational sanitation monitoring deficiencies were not identified and any corrective actions taken were not documented by the establishment personnel and SSOP records did not reflect the actual sanitary conditions observed in the establishment. B. GOI meat inspection officials were not monitoring/verifying the adequacy and effectiveness of the pre-operational and operational sanitation SSOP. This was a repeat deficiency from the last audit.

43 A. Edible and inedible product containers were not identified to prevent possible cross-contamination and/or cross utilization. B. Inedible product was not denatured/decharacterized before leaving establishment. This was a repeat deficiency from the last audit.

76 A. The FSIS auditors could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements. B. GOI meat inspection officials were not providing daily adequate inspection coverage. Inspector was visiting establishment three times a week (the establishment was working five days per week) and the duration of visits was one hour.

79. Species verification testing was not carried out as required by FSIS.

80. Because of gross product contamination and lack of compliance with daily pre-operational and operational sanitation/equivalent sanitation programs and procedures, inadequate inspectional controls, and noncompliance with basic FSIS regulatory requirements of HACCP program, the status of this establishment is not equivalent to that required in the U.S. program. All the above deficiencies were discussed with Dr. Maestripieri, IIC, and Dr. Pietro Noe and they agreed to remove Establishment 989-L from the list of establishments eligible to export meat and meat products to the United States, effective November 16, 2001.

82. This establishment did <u>not</u> meet some the the FSIS basic regulatory requirements of the HACCP program. In addition, the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation: the hazard analysis had not beer conducted or was not complete; the intended use of the product or end used had not been identified; there was not a HACCP plan for each product where a hazard had been identified; all hazards identified were not addressed by a CCP; there was not a critical limit and/or monitoring frequency for each CCP; there was no description of corrective action to be taken when a critical limit was exceeded; the HACCP plan had not been validated using multiple monitoring results; the HACCP plan did not list the procedures to verify effective implementation and/or frequency of these procedures; there were no records produced for monitoring of the HACCP plan CCPs, or the records did not show actual values and observations; and (12) pre-shipment document reviews were not being conducted by establishment officials.

NOTE: This establishment was unacceptable during the last audit in May, 2001.

NOTE: The deficiencies listed above were not identified by either establishment or inspection personnel. Corrective action was not initiated until the need was identified by the FSIS auditor.

INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

12-12-01 | Est. 1170-L Brendolan Service SRL | COUNTRY: Italy

NAME OF REVIEWER: Dr. Oto Urban

NAME OF FOREIGN OFFICIAL: Dr. Ivonne Caliz

EVALUATION: [X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
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1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 O
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
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Chlorination procedures	02 O	Product reconditioning	31 A	Label approvals	58 M
Back siphonage prevention	03 O	Product transportation	32 N	Special label claims	59 O
Hand washing facilities	04 M	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 O
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 O
Pest --no evidence	07 A	Operational sanitation	35 M	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 O
Equipment approval	16 O	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
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Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 O	Imports	81 O
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	82 M
Personal hygiene practices	26 A	Ingredients identification	53 O		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 O		

FOREIGN PLANT REVIEW FORM (reverse)	12-12-01	Est. 1170-L Brendolan Service SRL	COUNTRY Italy
NAME OF REVIEWER Dr. Oto Urban	NAME OF FOREIGN OFFICIAL Dr. Ivonne Caliz	EVALUATION [X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable	

COMMENTS:

4 The flipping top on waste receptacles was observed at the hand washing facilities across the establishment. This deficiency was corrected immediately by the establishment management.

34, 35 The government inspector was performing pre-operational sanitation once in 14 days and operational sanitation once a week. The SSOP corrective action was not specific enough and the preventive action needs to be included. This was scheduled for correction by the establishment management.

43 The edible plastic container was observed to be set on the floor in the slicing room. This deficiency was corrected immediately by the establishment management. The inedible product was not denatured in this establishment.

58 The establishment label approval indicates the European Union number not the one approved for the U.S.A. This was scheduled to be corrected by the establishment management.

76a The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

76b Internal reviews were performed only four times per year.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation.

FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE: 11-28-01

ESTABLISHMENT NO. AND NAME: Est. 1217 Stagionatura Prosciutti Torione

Lesignanobagni

COUNTRY: Italy

NAME OF REVIEWER: Dr. Oto Urban

NAME OF FOREIGN OFFICIAL: Dr. Cesare Allodi

EVALUATION: [X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
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Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 O
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 O
Pest --no evidence	07 M	Operational sanitation	35 M	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 M	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 O
Equipment approval	16 O	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 M	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76 U
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 O A
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	82 M
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 O		

FOREIGN PLANT REVIEW FORM (reverse)	11-28-01	Est. 1217 Stagionatura Prosciutti Torione	COUNTRY Italy
NAME OF REVIEWER Dr. Oto Urban	NAME OF FOREIGN OFFICIAL Dr. Cesare Allodi	EVALUATION [X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable	

COMMENTS:

7, 9 Insectocutors were located over the product traffic areas in the receiving, drying and shipping rooms. This was scheduled for correction by the establishment.

17 The ceiling over the product was crumbling in two places in the drying room. Product was moved away from the affected area and this deficiency was scheduled for correction by the establishment officials.

34, 35 The government inspector was performing pre-operational sanitation twice a year and operational sanitation twice a week for the duration of the visit of one to two hours. The pre-operational preventive action was missing.

43 The inedible product was not denatured at this establishment.

76. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation.

FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

12-03-01

Est. 1223-L Prosciuttificio MOZZANI S.P.A.

Felino

COUNTRY
Italy

NAME OF REVIEWER
Dr. Oto Urban

NAME OF FOREIGN OFFICIAL
Dr. Cesare Allodi

EVALUATION
[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 A
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 N	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 O
Sanitizers	05 M	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 O
Pest --no evidence	07 A	Operational sanitation	35 M	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
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FOREIGN PLANT REVIEW FORM (reverse)	12-03-01	Est. 1223-L Prosciuttificio MOZZANI S.P.A.	COUNTRY Italy
NAME OF REVIEWER Dr. Oto Urban	NAME OF FOREIGN OFFICIAL Dr. Cesare Allodi	EVALUATION [X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable	

COMMENTS:

5 The water temperature in both sanitizers was below the required temperature of 82C in the deboning room. This deficiency was corrected immediately by the establishment officials.

26 The box with strings destined to be used for the edible product were stored on the floor. This deficiency was corrected immediately by the establishment management.

34, 35 The government inspector was performing pre-operational sanitation twice a year and operational sanitation once a week.

43 The inedible product was not denatured in this establishment.

76. The FSIS auditor could find little evidence that the official veterinarian in charge of the establishment was accountable to higher levels of supervision by the central meat inspection authority. It was not clear who would be responsible for the implementation of corrective actions in the event that the official veterinarian's performance did not meet requirements.

82. The establishment's HACCP program met the basic requirements, but the HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation.

Country Response Not Received